

2022/0272 (COD)

Proposal for a

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on horizontal cybersecurity requirements for products with digital elements, and amending  
Regulation (EU) 2019/1020 and Directive (EU) 2020/1828**

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>1</sup>,

Having regard to the opinion of the Committee of the Regions<sup>2</sup>,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) It is necessary to improve the functioning of the internal market by laying down a uniform legal framework for essential cybersecurity requirements for placing products with digital elements on the Union market. Two major problems adding costs for users and society should be addressed: a low level of cybersecurity of products with digital elements, reflected by widespread vulnerabilities and the insufficient and inconsistent provision of security updates to address them, and an insufficient understanding and access to information by users, preventing them from choosing products with adequate cybersecurity properties or using them in a secure manner.

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<sup>1</sup> OJ C , , p. .

<sup>2</sup> OJ C , , p. .

- (2) This Regulation aims to set the boundary conditions for the development of secure products with digital elements by ensuring that hardware and software products are placed on the market with fewer vulnerabilities and that manufactures take security seriously throughout a product's life cycle. It also aims to create conditions allowing users to take cybersecurity into account when selecting and using products with digital elements.
- (3) The relevant Union legislation that is currently in force comprises several sets of horizontal rules that address certain aspects linked to cybersecurity from different angles, including measures to improve the security of the digital supply chain. However, the existing Union legislation related to cybersecurity, including ~~{Directive (EU) 2022/2555XXX/XXXX (NIS2)}~~ **of the European Parliament and of the Council**<sup>3</sup> and Regulation (EU) 2019/881 of the European Parliament and of the Council<sup>4</sup> does not directly cover mandatory requirements for the security of products with digital elements.
- (4) While the existing Union legislation applies to certain products with digital elements, there is no horizontal Union regulatory framework establishing comprehensive cybersecurity requirements for all products with digital elements. The various acts and initiatives taken thus far at Union and national levels only partially address the identified cybersecurity-related problems and risks, creating a legislative patchwork within the internal market, increasing legal uncertainty for both manufacturers and users of those products and adding an unnecessary burden on companies to comply with a number of requirements for similar types of products. The cybersecurity of these products has a particularly strong cross-border dimension, as products manufactured in one country are often used by organisations and consumers across the entire internal market. This makes it necessary to regulate the field at Union level. The Union regulatory landscape should be harmonised by introducing cybersecurity requirements for products with digital elements. In addition, certainty for **economic** operators and users should be ensured across the Union, as well as a better harmonisation of the single market, creating more viable conditions for **economic** operators aiming at entering the Union market.
- (5) At Union level, various programmatic and political documents, such as the EU's Cybersecurity Strategy for the Digital Decade<sup>5</sup>, the Council Conclusions of 2 December 2020 and of 23 May 2022 or the Resolution of the European Parliament of 10 June 2021,<sup>6</sup> have called for specific Union cybersecurity requirements for digital or connected products, with several countries around the world introducing measures to address this issue on their own initiative. In the final report of the Conference on the Future of Europe,<sup>7</sup> citizens called for "a stronger role for the EU in countering cybersecurity threats".
- (6) To increase the overall level of cybersecurity of all products with digital elements placed on the internal market, it is necessary to introduce objective-oriented and technology-neutral essential cybersecurity requirements for these products that apply horizontally.

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<sup>3</sup> **Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive) (OJ L 333, 27.12.2022, p. 80).**

<sup>4</sup> Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).

<sup>5</sup> JOIN(2020) 18 final, <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=JOIN:2020:18:FIN>.

<sup>6</sup> 2021/2568(RSP), [https://www.europarl.europa.eu/doceo/document/TA-9-2021-0286\\_EN.html](https://www.europarl.europa.eu/doceo/document/TA-9-2021-0286_EN.html).

<sup>7</sup> *Conference on the Future of Europe – Report on the Final Outcome*, May 2022, Proposal 28(2). The Conference was held between April 2021 and May 2022. It was a unique, citizen-led exercise of deliberative democracy at the pan-European level, involving thousands of European citizens as well as political actors, social partners, civil society representatives and key stakeholders.

- (7) Under certain conditions, all products with digital elements integrated in or connected to a larger electronic information system can serve as an attack vector for malicious actors. As a result, even hardware and software considered as less critical can facilitate the initial compromise of a device or network, enabling malicious actors to gain privileged access to a system or move laterally across systems. Manufacturers should therefore ensure that all connectable products with digital elements are designed and developed in accordance with essential requirements laid down in this Regulation. This includes both products that can be connected physically via hardware interfaces and products that are connected logically, such as via network sockets, pipes, files, application programming interfaces or any other types of software interface. As cybersecurity threats can propagate through various products with digital elements before reaching a certain target, for example by chaining together multiple vulnerability exploits, manufacturers should also ensure the cybersecurity of those products that are only indirectly connected to other devices or networks.
- (8) By setting cybersecurity requirements for placing on the market products with digital elements, the cybersecurity of these products for consumers and for businesses alike will be enhanced. This also includes requirements for placing on the market consumer products with digital elements intended for vulnerable consumers, such as toys and baby monitors. **Similarly the products with digital elements listed in Annex III and Annex IIIa to this Regulation are also relevant for consumer products. The stricter conformity assessment procedure that these products are required to comply with will contribute to prevent negative impacts of the exploitation of potential cybersecurity vulnerabilities on consumers. For instance, products with digital elements listed in Annex III and Annex IIIa, such as microprocessors, microcontrollers and operating systems, will typically be components that play an essential role for the cybersecurity of consumer products, including smart home products with safety functionalities, such as door locks and alarm systems, connected products for children, including toys and baby monitors, and wearable technology and other connected health devices.**
- (9) This Regulation ensures a high level of cybersecurity of products with digital elements. ~~It does not regulate services, such as Software-as-a-Service (SaaS), except for~~ **applies to** remote data processing solutions relating to a product with digital elements, ~~understood~~ **defined** as any data processing at a distance for which the software **or hardware** is designed and developed by the manufacturer of the product concerned or under the responsibility of that manufacturer, and the absence of which would prevent such a product with digital elements from performing one of its functions. **Software-as-a-Service (SaaS) solutions constitute remote data processing solutions within the meaning of this Regulation only if they meet that definition. For example, websites that do not support the functionality of a product with digital elements, or cloud services designed and developed outside the responsibility of a manufacturer of a product with digital elements are not in the scope of this Regulation.** ~~{Directive (EU) 2022/2555XXX/XXXX (NIS2)}~~ puts in place cybersecurity and incident reporting requirements for essential and important entities, such as critical infrastructure, with a view to increasing the resilience of the services they provide. ~~{Directive (EU) 2022/2555XXX/XXXX (NIS2)}~~ applies to cloud computing services and cloud service models, such as SaaS. All entities providing cloud computing services in the Union ~~that meet or exceed the threshold for~~ **which qualify as medium-sized enterprises under Article 2 of the Annex to Commission Recommendation 2003/361/EC<sup>8</sup>, or exceed the ceilings for medium-sized enterprises provided for in paragraph 1 of that Article,** fall in the scope of that Directive.

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8 Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

- (9a) The definition of products with digital elements also includes remote data processing solutions to ensure that such products are adequately secured in their entirety by their manufacturers, irrespective of whether data is processed or stored locally on the user's device or remotely by the manufacturer. The processing or storage at a distance is covered only in so far as necessary for a product with digital elements to perform its functions. This could for instance be the case where a hardware device requires access to an application programming interface or a database developed by the manufacturer. For example, many smart home devices are designed to communicate with a cloud service provided by the manufacturer, which enables users to control and monitor the devices at a distance using a mobile application. In such case, the cloud service is therefore in the scope of this Regulation as a remote data processing solution. The requirements concerning the remote data processing solutions under the scope of this Regulation do not therefore entail technical, operational and organisational measures aimed at managing the risks posed to the security of their network and information systems as a whole.**
- (9b) In line with the objective of this Regulation to remove obstacles to the free movement of products with digital elements, Member States should not impede, for the matters covered by this Regulation, the making available on the market of products with digital elements which comply with this Regulation. Therefore, for matters harmonised by this Regulation, Member States cannot impose further cybersecurity requirements for the making available on the market of products with digital elements. Any entity can however establish additional requirements to those laid down by this Regulation for the procurement or use of those products for their specific purposes and can therefore choose to use products with digital elements that meet stricter or more specific cybersecurity requirements than those applicable for the making available on the market under this Regulation. Furthermore, Directive (EU) 2022/2555 sets out cybersecurity risk-management measures for essential and important entities that could entail supply chain security measures that require the use of products with digital elements meeting stricter cybersecurity requirements than those laid down by this Regulation. In line with Directive (EU) 2022/2555 and its minimum harmonisation principle, Member States may therefore impose additional or stricter cybersecurity requirements for the use of ICT products by essential or important entities under the scope of that Directive in order to ensure a higher level of cybersecurity, provided that such requirements are consistent with Member States' obligations laid down in Union law. Matters not covered by this Regulation can include non-technical factors relating to products with digital elements and the manufacturers thereof. Member States may therefore lay down national measures, including restrictions on products with digital elements or suppliers of such products, that take account of non-technical factors. National measures relating to such factors must comply with Union law.**
- (9c) This Regulation should be without prejudice to the Member States' prerogatives to take measures safeguarding national security, in compliance with Union law. Member States should be able to subject products with digital elements that will be used for military, defence or national security purposes, to additional measures.**

- (10) ~~In order not to hamper innovation or research, free and open-source software developed or supplied outside the course of a commercial activity should not be covered by this Regulation. This is in particular the case for software, including its source code and modified versions, that is openly shared and freely accessible, usable, modifiable and redistributable. In the context of software, a commercial activity might be characterized not only by charging a price for a product, but also by charging a price for technical support services, by providing a software platform through which the manufacturer monetises other services, or by the use of personal data for reasons other than exclusively for improving the security, compatibility or interoperability of the software.~~

**This Regulation applies only to products with digital elements made available on the market, hence supplied for distribution or use on the Union market in the course of a commercial activity. The supply in the course of a commercial activity might be characterized not only by charging a price for a product, but also by charging a price for technical support services when this does not serve only the recuperation of actual costs or pursues a profit or the intention to monetise, by providing a software platform through which the manufacturer monetises other services, or by requiring as a condition for use, the processing of personal data for reasons other than exclusively for improving the security, compatibility or interoperability of the software. The circumstances under which the product has been developed, or how the development has been financed should not be taken into account when determining the commercial or non-commercial nature of that activity. Free and open-source software is understood as free software that is openly shared and freely accessible, usable, modified versions and redistributable, and which includes its source code and modified versions. Free and open-source software is developed, maintained, and distributed openly, including via online platforms. A package manager, code host or collaboration platform that facilitates the development and supply of software is only considered to be a distributor if they make this software available on the market and hence supply it for distribution or use on the Union market in the course of a commercial activity. Taking account of the above-mentioned elements determining the commercial nature of an activity, this Regulation should only apply to free and open-source software that is supplied in the course of a commercial activity. Products provided as part of the delivery of a service for which a fee is charged solely to recover the actual costs directly related to the operation of that service should, as it is, such as may be the case ~~of with~~ certain products provided by public administration entities, should not be considered on those grounds alone a commercial activity for the purposes of this Regulation.**

- (11) A secure Internet is indispensable for the functioning of critical infrastructures and for society as a whole. ~~{Directive (EU) 2022/2555XXX/XXXX (NIS2)}~~ aims at ensuring a high level of cybersecurity of services provided by essential and important entities, including digital infrastructure providers that support core functions of the open Internet, ensure Internet access and Internet services. It is therefore important that the products with digital elements necessary for digital infrastructure providers to ensure the functioning of the Internet are developed in a secure manner and that they comply with well-established Internet security standards. This Regulation, which applies to all connectable hardware and software products, also aims at facilitating the compliance of digital infrastructure providers with the supply chain requirements under ~~the {Directive (EU) 2022/2555XXX/XXXX (NIS2)}~~ by ensuring that the products with digital elements that they use for the provision of their services are developed in a secure manner and that they have access to timely security updates for such products.
- (11a) **One of the most important measures for users to take in order to protect their products with digital elements from cyberattacks is to install the latest available security updates as soon as possible. Manufacturers should therefore design their products and create processes to ensure that products with digital elements include functions that enable the notification, distribution, download and installation of security updates automatically. They should also provide the possibility to approve the download and installation of the security updates as a final step, as well as clear instructions on how users can opt out of automatic updates. The requirements relating to automatic updates laid down in Annex I of this Regulation are not applicable to products primarily intended to be integrated as components into other products. They also do not apply to products with digital elements for which users would not reasonably expect automatic updates, including products with digital elements intended to be used in professional ICT-networks, and especially in critical and industrial environments where an automatic update could cause interference with operations ~~such as in industrial environments~~. Irrespective of whether a product with digital elements is designed to receive automatic updates or not, its manufacturer should inform users about vulnerabilities and make security updates available without delay.**
- (12) Regulation (EU) 2017/745 of the European Parliament and of the Council<sup>9</sup> lays down rules on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council<sup>10</sup> lays down rules on *in vitro* diagnostic medical devices. Both Regulations address cybersecurity risks and follow particular approaches that are also addressed in this Regulation. More specifically, Regulations (EU) 2017/745 and (EU) 2017/746 lay down essential requirements for medical devices that function through an electronic system or that are software themselves. Certain non-embedded software and the whole life cycle approach are also covered by those Regulations. These requirements mandate manufacturers to develop and build their products by applying risk management principles and by setting out requirements concerning IT security measures, as well as corresponding conformity assessment procedures. Furthermore, specific guidance on cybersecurity for medical devices is in place since December 2019, providing manufacturers of medical devices, including *in vitro* diagnostic devices, with guidance on how to fulfil all the relevant essential

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<sup>9</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

<sup>10</sup> Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

requirements of Annex I to those Regulations with regard to cybersecurity.<sup>11</sup> Products with digital elements to which either of those Regulations apply should therefore not be subject to this Regulation.

- (13) Regulation (EU) 2019/2144 of the European Parliament and of the Council<sup>12</sup> establishes requirements for the type-approval of vehicles, and of their systems and components, introducing certain cybersecurity requirements, including on the operation of a certified cybersecurity management system, on software updates, covering organisations policies and processes for cyber risks related to the entire life cycle of vehicles, equipment and services in compliance with the applicable United Nations regulations on technical specifications and cybersecurity<sup>13</sup>, and providing for specific conformity assessment procedures. In the area of aviation, the principal objective of Regulation (EU) 2018/1139 of the European Parliament and of the Council<sup>14</sup> is to establish and maintain a high uniform level of civil aviation safety in the Union. It creates a framework for essential requirements for airworthiness for aeronautical products, parts, equipment, including software that take into account obligations to protect against information security threats. Products with digital elements to which Regulation (EU) 2019/2144 applies and those products certified in accordance with Regulation (EU) 2018/1139 are therefore not subject to the essential requirements and conformity assessment procedures set out in this Regulation., The certification process under Regulation (EU) 2018/1139 ensures the level of assurance aimed for by this Regulation.
- (14) This Regulation lays down horizontal cybersecurity rules which are not specific to sectors or certain products with digital elements. Nevertheless, sectoral or product-specific Union rules could be introduced, laying down requirements that address all or some of the risks covered by the essential requirements laid down by this Regulation. In such cases, the application of this Regulation to products with digital elements covered by other Union rules laying down requirements that address all or some of the risks covered by the essential requirements set out in Annex I of this Regulation may be limited or excluded where such limitation or exclusion is consistent with the overall regulatory framework applying to those products and where the sectoral rules achieve **at least** the same level of protection as the one provided for by this Regulation. ~~The Commission is empowered to adopt delegated acts to amend this Regulation by identifying such products and rules.~~ For existing Union legislation where such limitations or exclusions should apply, this Regulation contains specific provisions to clarify its relation with that Union legislation.

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<sup>11</sup> MDCG 2019-16, endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745.

<sup>12</sup> Regulation (EU) 2019/2144 of the European Parliament and of the Council of 27 November 2019 on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/858 of the European Parliament and of the Council and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 of the European Parliament and of the Council and Commission Regulations (EC) No 631/2009, (EU) No 406/2010, (EU) No 672/2010, (EU) No 1003/2010, (EU) No 1005/2010, (EU) No 1008/2010, (EU) No 1009/2010, (EU) No 19/2011, (EU) No 109/2011, (EU) No 458/2011, (EU) No 65/2012, (EU) No 130/2012, (EU) No 347/2012, (EU) No 351/2012, (EU) No 1230/2012 and (EU) 2015/166 (*OJ L 325, 16.12.2019, p. 1*).

<sup>13</sup> UN Regulation No 155 – Uniform provisions concerning the approval of vehicles with regard to cybersecurity and cybersecurity management system [2021/387].

<sup>14</sup> Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (*OJ L 212, 22.8.2018, p. 1*).

- (15) Delegated Regulation (EU) 2022/30 specifies that the essential requirements set out in Article 3(3), point (d) (network harm and misuse of network resources), point (e) (personal data and privacy) and point (f) (fraud) of Directive 2014/53/EU apply to certain radio equipment. [Commission implementation decision XXX/2022 on a standardisation request to the European Standardisation Organisations] lays down requirements for the development of specific standards further specifying how these three essential requirements should be addressed. The essential requirements laid down by this Regulation include all the elements of the essential requirements referred to in Article 3(3), points (d), (e) and (f) of Directive 2014/53/EU. Further, the essential requirements laid down in this Regulation are aligned with the objectives of the requirements for specific standards included in that standardisation request. Therefore, if the Commission repeals or amends Delegated Regulation (EU) 2022/30 with the consequence that it ceases to apply to certain products subject to this Regulation, the Commission and the European Standardisation Organisations should take into account the standardisation work carried out in the context of Commission Implementing Decision C(2022)5637 on a standardisation request for the RED Delegated Regulation 2022/30 in the preparation and development of harmonised standards to facilitate the implementation of this Regulation.
- (16) Directive 85/374/EEC<sup>15</sup> is complementary to this Regulation. That Directive sets out liability rules for defective products so that injured persons can claim compensation when a damage has been caused by defective products. It establishes the principle that the manufacturer of a product is liable for damages caused by a lack of safety in their product irrespective of fault ('strict liability'). Where such a lack of safety consists in a lack of security updates after placing the product on the market, and this causes damage, the liability of the manufacturer could be triggered. Obligations for manufacturers that concern the provision of such security updates should be laid down in this Regulation.
- (17) This Regulation should be without prejudice to Regulation (EU) 2016/679 of the European Parliament and of the Council<sup>16</sup>, including to provisions for the establishment of data protection certification mechanisms and of data protection seals and marks, for the purpose of demonstrating compliance of processing operations by controllers and processors with that Regulation. Such operations could be embedded in a product with digital elements. Data protection by design and by default, and cybersecurity in general, are key elements of Regulation (EU) 2016/679. By protecting consumers and organisations from cybersecurity risks, the essential cybersecurity requirements laid down in this Regulation, are also to contribute to enhancing the protection of personal data and privacy of individuals. Synergies on both standardisation and certification on cybersecurity aspects should be considered through the cooperation between the Commission, the European Standardisation Organisations, the European Union Agency for Cybersecurity (ENISA), the European Data Protection Board (EDPB) established by Regulation (EU) 2016/679, and the national data protection supervisory authorities. Synergies between this Regulation and the Union data protection law should also be created in the area of market surveillance and enforcement. To this end, national market surveillance authorities appointed under this Regulation should cooperate with authorities supervising Union data protection law. The latter should also have access to information relevant for accomplishing their tasks.

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<sup>15</sup> Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.85).

<sup>16</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).



- (18) To the extent that ~~their~~ **products with digital elements** fall within the scope of ~~this Regulation, issuers of European Digital Identity Wallets as referred to in Article [Article 6a(2) of this Regulation and~~ Regulation (EU) No 910/2014, as amended by Proposal for a Regulation amending Regulation (EU) No 910/2014 as regards establishing a framework for a European Digital Identity], **these products** should comply with both the horizontal essential requirements established by this Regulation and the specific security requirements established by ~~Article [Article 6a of Regulation (EU) No 910/2014, as amended by Proposal for a Regulation amending Regulation (EU) No 910/2014 as regards establishing a framework for a European Digital Identity].~~ ~~In order to facilitate compliance, wallet issuers should be able to demonstrate the compliance of European Digital Identity Wallets with the requirements set out respectively in both acts by certifying their products under a European cybersecurity certification scheme established under Regulation (EU) 2019/881 and for which the Commission specified via implementing act a presumption of conformity for this Regulation, in so far as the certificate, or parts thereof, covers those requirements.~~
- (18a) **When integrating components sourced from third parties in products with digital elements during the design and development phase, manufacturers should exercise due diligence. The appropriate level of due diligence measures should be informed by the nature and level of the cybersecurity risk associated with the component and, for this purpose, take into account specific factors, such as the way in which the component contributes to the functionality of the product and the extent to which it has access to data processed by the product with digital elements. Depending on the risk, due diligence measures could include verifying that the manufacturer of a component has demonstrated conformity with this Regulation, verifying that a component is free from vulnerabilities registered in publicly accessible vulnerability databases, or verifying that a component receives regular security updates. The vulnerability handling obligations in this Regulation, which the manufacturers have to comply with when placing a product with digital elements on the market and for the expected product lifetime, apply to products with digital elements in their entirety, including to all integrated components.**
- ~~(19) Certain tasks provided for in this Regulation should be carried out by ENISA, in accordance with Article 3(2) of Regulation (EU) 2019/881. In particular, ENISA should receive notifications from manufacturers of actively exploited vulnerabilities contained in products with digital elements, as well as incidents having an impact on the security of those products. ENISA should also forward these notifications to the relevant Computer Security Incident Response Teams (CSIRTs) or, respectively, to the relevant single points of contact of the Member States designated in accordance with Article [Article X] of Directive [Directive XXX / XXXX (NIS2)], and inform the relevant market surveillance authorities about the notified vulnerability. On the basis of the information it gathers, ENISA should prepare a biennial technical report on emerging trends regarding cybersecurity risks in products with digital elements and submit it to the Cooperation Group referred to in **established under Directive (EU) 2022/2555 [Directive XXX / XXXX (NIS2)].** Furthermore, considering its expertise and mandate, ENISA should be able to support the process for implementation of this Regulation. In particular, it should be able to propose joint activities to be conducted by market surveillance authorities based on indications or information regarding potential non-compliance with this Regulation of products with digital elements across several Member States or identify categories of products for which simultaneous coordinated control actions should be organised. In exceptional circumstances, at the request of the Commission, ENISA should be able to ~~conduct~~ **provide an analysis to support an** evaluations in respect of specific products with digital elements that present a significant cybersecurity risk, where an immediate intervention is required to preserve the~~

good functioning of the internal market. **[Entire recital to be re-evaluated in light of ENISA's role discussions]**

- (19a) **Actively exploited vulnerabilities concern instances where a manufacturer establishes that an attempted or successful security breach affecting its users or any other natural or legal persons has resulted from a malicious actor making use of a flaw in one of the products with digital elements placed on the market by the manufacturer. An example of such a vulnerability could be the insufficient protection of a product against brute force attacks. Risks of reporting unpatched vulnerabilities should be minimized by technical measures and procedural agreements. Incidents having an impact on the security of the product with digital elements, on the other hand, refer to situations where a cybersecurity incident affects the development, production or maintenance processes of the manufacturer in such a way that it could result in an increased cybersecurity risk for users or other persons. An example of such incident is a security breach on the manufacturer's network allowing unauthorised persons to introduce malicious code into a product in development or into a release channel that provides users with automatic updates.**
- (20) Products with digital elements should bear the CE marking to indicate their conformity with this Regulation so that they can move freely within the internal market. Member States should not create unjustified obstacles to the placing on the market of products with digital elements that comply with the requirements laid down in this Regulation and bear the CE marking.
- (21) In order to ensure that manufacturers can release software for testing purposes before subjecting their products to conformity assessment, Member States should not prevent the making available of unfinished software, such as alpha versions, beta versions or release candidates, as long as the version is only made available for the time necessary to test it and gather feedback. Manufacturers should ensure that software made available under these conditions is only released following a risk assessment and that it complies to the extent possible with the security requirements relating to the properties of products with digital elements imposed by this Regulation. Manufacturers should also implement the vulnerability handling requirements to the extent possible. Manufacturers should not force users to upgrade to versions only released for testing purposes.
- (22) In order to ensure that products with digital elements, when placed on the market, do not pose cybersecurity risks to persons and organisations, essential requirements should be set out for such products. **These essential requirements, including vulnerability management handling requirements, apply to each individual product with digital elements when placed on the market, irrespective of whether the product with digital elements is manufactured as an individual unit or in series. For example, for a product type, each individual product with digital elements should have received all security patches or updates available to address relevant security issues at the time when it is placed on the market.** When the products are subsequently modified, by physical or digital means, in a way that is not foreseen by the manufacturer and that may imply that they no longer meet the relevant essential requirements, the modification should be considered as substantial. For example, software updates or repairs could be assimilated to maintenance operations provided that they do not modify a product already placed on the market in such a way that compliance with the applicable requirements may be affected, or that the intended **use purpose** for which the product has been assessed may be changed. As is the case for physical repairs or modifications, a product with digital elements ~~made available on the market~~ should be considered as substantially modified by a software change where the software update modifies the ~~original~~ intended **purpose** functions, type or performance of ~~the~~ **that** product and these changes were not foreseen in the initial risk assessment, or **where**

the nature of the hazard has changed or the level of risk has increased because of the software update, **and the product is made available on the market.**

- (22a) **Where security updates, which are designed to decrease the level of risk of a product with digital elements, do not modify the intended purpose of a product, they are not considered a substantial modification. For example, this could be the case where a security update addresses a known vulnerability. Where feature updates modify the original intended functions or the type or performance of a product, they should be considered a substantial modification, as the addition of new features typically leads to a broader attack surface, thereby increasing the risk. For example, this could be the case where a new input element is added to an application, requiring the manufacturer to ensure adequate input validation. In assessing whether a feature update is considered a substantial modification it is not relevant whether it is provided as a separate update or in combination with a security update.**
- (23) In line with the commonly established notion of substantial modification for products regulated by Union harmonisation legislation, whenever a substantial modification occurs that may affect the compliance of a product with this Regulation or when the intended purpose of that product changes, it is appropriate that the compliance of the product with digital elements is verified and that, where applicable, it undergoes a new conformity assessment. Where applicable, if the manufacturer undertakes a conformity assessment involving a third party, changes that might lead to substantial modifications should be notified to the third party.
- (24) Refurbishing, maintaining and repairing of a product with digital elements, as defined in the Regulation [Eco-design Regulation], does not necessarily lead to a substantial modification of the product, for instance if the intended ~~use~~ **purpose** and functionalities are not changed and the level of risk remains unaffected. However, upgrading a product by the manufacturer might lead to changes in the design and development of the product and therefore might affect the intended ~~use~~ **purpose** and the compliance of the product with the requirements set out in this Regulation.
- (25) Products with digital elements should be **included in Annex III of this Regulation**~~considered critical~~ if the negative impact of the exploitation of potential cybersecurity vulnerabilities in the product can be severe due to, amongst others, the cybersecurity-related functionality **or the central system function performed or a function having a significant risk of adverse effects in terms of its intensity and ability ~~the potential~~ to disrupt, control or cause damage to a large number of other products with digital elements through direct manipulation, such as a central system function.** ~~or the intended use.~~ In particular, vulnerabilities in products with digital elements that have a cybersecurity-related functionality, such as secure elements, can lead to a propagation of security issues throughout the supply chain. The severity of the impact of a cybersecurity incident may also increase when ~~taking into account the intended use of the product, such as in an industrial control setting or in the context of an essential entity of the type referred to in Annex [Annex I] to Directive [Directive XXX/ XXXX (NIS2)], or for the performance of critical or sensitive functions, such as processing of personal data~~ **the product primarily performs a central system function, including network management, configuration control, virtualisation or processing of personal data.**

- (26) ~~Critical~~ **Certain categories of products with digital elements should be subject to stricter conformity assessment procedures, while keeping a proportionate approach. For this purpose, ~~critical~~ those categories of products with digital elements should be divided into two classes, reflecting the level of cybersecurity risk linked to these categories of products. The categories of products with digital elements listed in class I of Annex III to this Regulation either have a cybersecurity-related functionality or primarily performs a central system function or a function which carries a significant risk of adverse effects in terms of its intensity and ability- having the potential to disrupt, control or cause damage to a large number of other products with digital elements through direct manipulation, such as a central system function. The categories of products with digital elements listed in class II of Annex III meet both these criteria. Cumulating these criteria indicates that a potential cyber incident involving products in class II might lead to greater negative impacts than an incident involving products in class I, for instance due to the nature of their cybersecurity-related function and the performance of a function which carries a significant risk of adverse effects, such as a central system function or intended use in sensitive environments, and therefore should undergo a stricter conformity assessment procedure.**
- (27) The categories of critical products with digital elements referred to in Annex III of this Regulation should be understood as the products which have the core functionality of the type that is listed in Annex III to this Regulation. For example, Annex III to this Regulation lists products which are defined by their core functionality as ~~general-purpose microprocessors~~ identity management systems software firewalls, intrusion detection or prevention systems in class II. As a result, ~~general-purpose microprocessors~~ firewalls, intrusion detection or prevention systems-identity management systems software are subject to mandatory third-party conformity assessment. This is not the case for other products not explicitly referred to in Annex III to this Regulation which may integrate a firewalls, intrusion detection or prevention systems-identity management systems software a general-purpose microprocessor. The Commission should adopt ~~delegated~~ an implementing acts [by 12 months since the entry into force of this Regulation] to specify the definitions of the product categories covered under class I and class II as set out in Annex III.
- (27a) **The categories of products with digital elements listed in Annex IIIa to this Regulation have a cybersecurity-related functionality and primarily perform a central system function or a function having the potential to disrupt, control or damage a large number of other products with digital elements through direct manipulation. Furthermore, those product categories are considered to be critical dependencies for entities of a type referred to in Annex I to Directive (EU) 2022/2555 and should therefore be considered as highly critical within the meaning of this Regulation. The categories of products with digital elements listed in Annex IIIa to this Regulation, due to their high criticality, already widely use various forms of certification, and are also covered by the European Common Criteria-based cybersecurity certification scheme set out in the [Commission Implementing Regulation (EU) No .../... of XXX on the European Common Criteria-based cybersecurity certification scheme] (EUCC). Therefore, in order to ensure a common adequate cybersecurity protection of these highly critical products with digital elements in the Union, it could be adequate and proportionate to subject these products, by means of a delegated act, to mandatory European cybersecurity certification where a relevant certification scheme covering those products is already in place and an impact assessment has been carried out by**

the Commission. The assessment of the potential market impact of the envisaged mandatory certification should consider both the supply and demand side, including whether there is sufficient demand for the products with digital elements concerned from both Member States and users, for European cybersecurity certification to be required, as well as the purposes for which the products are intended to be used, such as critical dependencies by entities of a type referred to in Annex I to Directive (EU) 2022/2555. The impact assessment should also analyse the potential effects of the mandatory certification on the availability of those products on the internal market, as well as, to the extent appropriate, the implementation capabilities of the Member States in relation to the relevant European cybersecurity certification schemes.

- (27aa) Delegated acts requiring mandatory European cybersecurity certification should specify the products with digital elements that have the core functionality of a product category listed in Annex IIIa that are to be subject to mandatory certification, as well as the assurance level required. The required assurance level, ‘substantial’ or ‘high’, should be proportionate to the level of cybersecurity risk associated with the product with digital elements. For instance, where the product has the core functionality of a product category listed in Annex IIIa and is intended for the use in a sensitive or critical environment, such as products intended for the use of entities of a type referred to in Annex I to Directive (EU) 2022/2555, it may require the highest assurance level.**
- (27ab)** In order to ensure a common adequate cybersecurity protection of highly critical products with digital elements in the Union, the Commission should also be empowered to adopt delegated acts to amend Annex IIIa by adding further or removing categories of highly critical products with digital elements for which the manufacturers could be required to obtain a European cybersecurity certificate under a European cybersecurity certification scheme pursuant to Regulation (EU) 2019/881 to demonstrate conformity with this Regulation. A new category of products with digital elements can be considered highly critical if there is a high critical dependency on it of entities of a type referred to in Annex I to Directive (EU) 2022/2555 or, if affected by cybersecurity incidents or when containing exploited vulnerabilities, this can lead to serious disruptions for critical supply chains. When assessing the need for adding or removing categories of highly critical products with digital elements by means of a delegated act, the Commission may take into account whether the Member States identified at national level products with digital elements that have a critical role for the resilience of entities of a type referred to in Annex I to Directive (EU) 2022/2555 and which increasingly face supply chain cyber attacks, with potential serious disruptive effects. Furthermore, the Commission may take into account the outcome of the Union level coordinated security risk assessment of critical supply chains as per Article 22 of Directive (EU) 2022/2555.
- (28)** This Regulation addresses cybersecurity risks in a targeted manner. Products with digital elements might, however, pose other safety risks, that are not related to cybersecurity. Those risks should continue to be regulated by other relevant Union ~~product~~ **harmonisation** legislation. If no other Union harmonisation legislation is applicable, they should be subject to Regulation (EU) 2023/988 of the European Parliament and of the Council<sup>17</sup> ~~{General~~

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<sup>17</sup> Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (OJ L 135, 23.5.2023, p. 1).

~~Product Safety Regulation~~]. Therefore, in light of the targeted nature of this Regulation, as a derogation from Article 2(1), third subparagraph, point (b), of Regulation (EU) 2023/988 [~~General Product Safety Regulation~~], Chapter III, Section 1, Chapters V and VII, and Chapters IX to XI of Regulation [~~General Product Safety Regulation~~] should apply to products with digital elements with respect to safety risks not covered by this Regulation, if those products are not subject to specific requirements imposed by other Union harmonisation legislation **as defined in within the meaning of Article 3, point (275) of Regulation (EU) 2023/988** ~~the General Product Safety Regulation~~].

- (29) Products with digital elements classified as high-risk AI systems according to Article 6 of Regulation<sup>18</sup> [the AI Regulation] which fall within the scope of this Regulation should comply with the essential requirements set out in this Regulation. When those high-risk AI systems fulfil the essential requirements of this Regulation, they should be deemed compliant with the cybersecurity requirements set out in Article [Article 15] of Regulation [the AI Regulation] in so far as those requirements are covered by the EU declaration of conformity or parts thereof issued under this Regulation. As regards the conformity assessment procedures relating to the essential cybersecurity requirements of a product with digital elements covered by this Regulation and classified as a high-risk AI system, the relevant provisions of Article 43 of Regulation [the AI Regulation] should apply as a rule instead of the respective provisions of this Regulation. However, this rule should not result in reducing the necessary level of assurance for ~~critical~~ products with digital elements covered by this Regulation **as referred to in Annex III**. Therefore, by way of derogation from this rule, high-risk AI systems that fall within the scope of the Regulation [the AI Regulation] and are also ~~qualified as critical~~ products with digital elements **as referred to in Annex III**, pursuant to this Regulation and to which the conformity assessment procedure based on internal control referred to in Annex VI of the Regulation [the AI Regulation] applies, should be subject to the conformity assessment provisions of this Regulation in so far as the essential requirements of this Regulation are concerned. In this case, for all the other aspects covered by Regulation [the AI Regulation] the respective provisions on conformity assessment based on internal control set out in Annex VI to Regulation [the AI Regulation] should apply.
- (30) **To the extent that The machinery products falling within the scope of Regulation (EU) 2023/1230 of the European Parliament and of the Council<sup>19</sup> [~~Machinery Regulation proposal~~] are products with digital elements within the meaning of this Regulation, manufacturers of these products should comply with both the essential requirements established by this Regulation and which are ~~products with digital elements within the meaning of this Regulation and for which a declaration of conformity has been issued on the basis of this Regulation should be deemed to be in conformity with the essential health and safety requirements set out in~~ **the Regulation (EU) 2023/1230** [~~Machinery Regulation proposal~~]. The essential requirements under this Regulation and certain essential requirements of **Regulation (EU) 2023/1230** ~~the [~~Machinery Regulation proposal~~]~~ might address similar aspects. For instance, compliance with the essential requirements under this Regulation could facilitate the compliance with the essential requirements related to cybersecurity regarding the protection against corruption and safety and reliability of control systems set out in **sections 1.1.9 and 1.2.1 of** [~~Annex III, sections 1.1.9 and 1.2.1] of the~~ **to Regulation (EU) 2023/1230** [~~Machinery Regulation proposal~~].;**

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<sup>18</sup> Regulation [the AI Regulation].

<sup>19</sup> **Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (OJ L 165, 29.6.2023, p. 1).**

as regards protection against corruption and safety and reliability of control systems in so far as the compliance with those requirements is demonstrated by the EU declaration of conformity issued under this Regulation. A manufacturer may identify such synergies during the risk assessment process as foreseen under ~~the Machinery Regulation (EU) 2023/1230 proposal~~. Furthermore, the Commission and the European Standardisation Organisations should take into account this Regulation in the preparation and development of harmonised standards to facilitate the implementation of Regulation (EU) 2023/1230~~the Machinery Regulation proposal~~ as regards in particular the cybersecurity aspects related to the protection against corruption and safety and reliability of control systems set out in Sections 1.1.9 and 1.2.1 of Annex III to that Regulation~~Machinery Regulation proposal~~.

- (31) Regulation [European Health Data Space Regulation proposal] complements the essential requirements laid down in this Regulation. The electronic health record systems ('EHR systems') falling under the scope of Regulation [European Health Data Space Regulation proposal] which are products with digital elements within the meaning of this Regulation should therefore also comply with the essential requirements set out in this Regulation. Their manufacturers should demonstrate conformity as required by Regulation [European Health Data Space Regulation proposal]. To facilitate compliance, manufacturers may draw up a single technical documentation containing the elements required by both legal acts. As this Regulation does not cover SaaS as such, EHR systems offered through the SaaS licensing and delivery model are not within the scope of this Regulation. Similarly, EHR systems that are developed and used in-house are not within the scope of this Regulation, as they are not placed on the market.
- (32) In order to ensure that products with digital elements are secure both at the time of their placing on the market as well as throughout their life-cycle, it is necessary to lay down essential requirements for vulnerability handling and essential cybersecurity requirements relating to the properties of products with digital elements. While manufacturers should comply with all essential requirements related to vulnerability handling and ensure that all their products are delivered without any known exploitable vulnerabilities, they should determine which other essential requirements related to the product properties are relevant for the concerned type of product. For this purpose, manufacturers should undertake an assessment of the cybersecurity risks associated with a product with digital elements to identify relevant risks and relevant essential requirements and in order to appropriately apply suitable harmonised standards or common specifications.
- (32a) **When assessing the risks associated with a product with digital elements, manufacturers should take into account the potential systemic impact of a vulnerability on consumers and organisations. Where a product with digital elements is used only by a limited number of users or in less critical or sensitive environments, as it is often the case with products with digital elements placed on the market by micro and small enterprises, manufacturers should be able to consider the risk of such a systemic impact as low.**
- (32aa) **Where certain essential requirements are not applicable to a product with digital elements, the manufacturer should include a clear justification in the cybersecurity risk assessment included in the technical documentation. This could be the case where an essential requirement would be incompatible with the nature of a product with digital elements. For example, the intended purpose of a product may require the manufacturer to follow widely recognised interoperability standards even if their security features are no longer considered state of the art. Similarly, other Union legislation may require manufacturers to apply specific interoperability requirements.**



**This is for example the case of Commission Implementing Regulation (EU) 2019/838 on technical specifications for vessel tracking and tracing systems and repealing Regulation (EC) No 415/2007, which specifies how AIS transponders should communicate with one another. Where an essential requirement is not applicable to a product with digital elements, but the manufacturer has identified cybersecurity risks in relation to this essential requirement, it should take measures to address those risks by other means, for instance by limiting the intended purpose of the product to trusted environments or by informing the users about those risks.**

- (33) In order to improve the security of products with digital elements placed on the internal market it is necessary to lay down essential requirements. These essential requirements should be without prejudice to the ~~EU~~ **Union level** coordinated **security** risk assessments of critical supply chains established **pursuant to** ~~by~~ ~~[Article 22X]~~ of Directive (EU) 2022/2555 ~~[Directive XXX/XXXX (NIS2)]~~<sup>20</sup>, which take into account both technical and, where relevant, non-technical risk factors, such as undue influence by a third country on suppliers. Furthermore, it should be without prejudice to the Member States' prerogatives to lay down additional requirements that take account of non-technical factors for the purpose of ensuring a high level of resilience, including those defined in Recommendation (EU) 2019/534, in the ~~Union-wide~~ **EU** coordinated risk assessment of **the cybersecurity of 5G networks** ~~security~~ and in the EU Toolbox on 5G cybersecurity agreed by the NIS Cooperation Group as ~~referred to in~~ ~~[established under Directive (EU) 2022/2555 XXX/XXXX (NIS2)]~~.
- (33a) **To ensure that the expected product lifetime specified by manufacturers are is sufficiently aligned within each category of products with digital elements, market surveillance authorities, through the dedicated administrative cooperation group (ADCO) established by this Regulation, should consider publishing, with the support of the Commission, statistics about the average expected product lifetime, as specified by manufacturers, per category of products with digital elements.**
- (34)<sup>21</sup> To ensure that the ~~national~~ CSIRTs and the ~~single point of contacts~~ designated as **coordinators pursuant to** ~~in accordance with Article 12(1) [Article X]~~ of Directive (EU) 2022/2555 ~~[Directive XX/XXXX (NIS2)]~~ are provided with the information necessary to fulfil their tasks and raise the overall level of cybersecurity of essential and important entities, and to ensure the effective functioning of market surveillance authorities, manufacturers of products with digital elements should notify **vulnerabilities that are being actively exploited to any CSIRT within a Member State, provided that it is a CSIRT on the territory of which their product with digital elements is made available that is designated as coordinator pursuant to Article 12(1) of Directive (EU) 2022/2555.** ~~ENISA vulnerabilities that are being actively exploited.~~ As most products with digital elements are marketed across the entire internal market, any exploited vulnerability in a product with digital elements should be considered a threat to the functioning of the internal market. Manufacturers should also consider disclosing fixed vulnerabilities to the European vulnerability database established under Directive (EU) 2022/2555 ~~[Directive XX/XXXX (NIS2)]~~ and managed by ENISA or under any other publicly accessible vulnerability database, **as well as machine-readable advisories.**

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<sup>20</sup> ~~Directive XXX of the European Parliament and of the Council of [date] [on measures for a high common level of cybersecurity across the Union, repealing Directive (EU) 2016/1148 (OJ L xx, date, p.x)].~~

<sup>21</sup> Will be amended when article 11 is set.

- (35)<sup>22</sup> Manufacturers should also report **any incident having an impact on the security of the product with digital elements to any CSIRT within a Member State, provided that it is a CSIRT on the territory of which their product with digital elements is made available that is designated as coordinator pursuant to Article 12(1) of Directive (EU) 2022/2555**, ~~to ENISA any incident having an impact on the security of the product with digital elements.~~ Notwithstanding the incident reporting obligations in Directive (EU) 2022/2555 ~~[Directive XXX/XXXX (NIS2)]~~ for essential and important entities, it is crucial for CSIRTs, ~~ENISA, the single points of contact~~ **designated as coordinators pursuant to Article 12 (1) [Article X] of Directive (EU) 2022/2555 [Directive XXX/XXXX (NIS2)]** and the market surveillance authorities to receive information from the manufacturers of products with digital elements allowing them to assess the security of these products. In order to ensure that users can react quickly to incidents having an impact on the security of their products with digital elements, manufacturers should also inform their users about any such incident and, where applicable, about any corrective measures that the users can deploy to mitigate the impact of the incident, for example by publishing relevant information on their websites or, where the manufacturer is able to contact the users and where justified by the risks, by reaching out to the users directly.
- (35a) In exceptional circumstances, the initial recipient of a notification should be able to decide to delay its dissemination via the single reporting platform where this can be justified on cybersecurity related grounds and for a period of time that is strictly necessary, in particular where manufacturers demonstrate that such a delay is justified. The CSIRTs network should develop guidelines on the terms and conditions for when cybersecurity related grounds could be applied. Examples of cybersecurity related grounds include an ongoing coordinated vulnerability disclosure procedure or situations in which a manufacturer is expected to provide a mitigating measure shortly and the cybersecurity risks of an immediate dissemination via the platform outweigh its benefits.**
- (36) Manufacturers of products with digital elements should put in place coordinated vulnerability disclosure policies to facilitate the reporting of vulnerabilities by individuals or entities. A coordinated vulnerability disclosure policy should specify a structured process through which vulnerabilities are reported to a manufacturer in a manner allowing the manufacturer to diagnose and remedy such vulnerabilities before detailed vulnerability information is disclosed to third parties or to the public. **Moreover, manufacturers should also consider publishing their security policies in machine-readable format.** Given the fact that information about exploitable vulnerabilities in widely used products with digital elements can be sold at high prices on the black market, manufacturers of such products should be able to use programmes, as part of their coordinated vulnerability disclosure policies, to incentivise the reporting of vulnerabilities by ensuring that individuals or entities receive recognition and compensation for their efforts (so-called ‘bug bounty programmes’).
- (37) In order to facilitate vulnerability analysis, manufacturers should identify and document components contained in the products with digital elements, including by drawing up a software bill of materials. A software bill of materials can provide those who manufacture, purchase, and operate software with information that enhances their understanding of the supply chain, which has multiple benefits, most notably it helps manufacturers and users to track known newly emerged vulnerabilities and risks. It is of particular importance for manufacturers to ensure that their products do not contain vulnerable components developed by third parties.

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<sup>22</sup> Will be amended when article 11 is set

- (37a) **Under the new complex business models linked to online sales, the same entity can provide a variety of services. Depending on the nature of the services provided in relation to a given product with digital elements, the same entity may fall within different categories of business models. Where an entity provides only online intermediation services for a given product with digital elements and is merely a provider of an online marketplace, as defined by Article 3, point (14),~~[XXX]~~<sup>23</sup> of Regulation (EU) 2023/988, it would not qualify as one of the types of economic operator defined in this Regulation. A provider of an online marketplace means a provider of an intermediary service using an online interface, which allows consumers to conclude distance contracts with traders for the sale of products, while online interface means any software, including a website, part of a website or an application, including mobile applications. In case the same entity is a provider of an online marketplace and also acts as an economic operator as defined in this Regulation for the sale of particular products with digital elements, it would qualify also as the relevant type of economic operator for the purposes of this Regulation. In such a case, the entity in question would therefore have to comply with the obligations laid down in this Regulation for the relevant type of economic operator. For instance, if the provider of the online marketplace also distributes a product with digital elements, then, with respect to the sale of that product, it would be considered to be a distributor. Similarly, if the entity in question sells its own branded products with digital elements, it would qualify as a manufacturer and would thus have to comply with the applicable requirements for manufacturers. Also some entities can qualify as fulfilment service providers as defined by Article 3(11) of Regulation (EU) 2019/1020 if they offer such services. Such cases would need to be assessed on a case-by-case basis.**
- (38) In order to facilitate assessment of conformity with the requirements laid down by this Regulation, there should be a presumption of conformity for products with digital elements which are in conformity with harmonised standards, which translate the essential requirements of this Regulation into detailed technical specifications, and which are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>24</sup>. Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Regulation.
- (39) Regulation (EU) 2019/881 establishes a voluntary European cybersecurity certification framework for ICT products, processes and services. European cybersecurity certification schemes can cover products with digital elements covered by this Regulation. This Regulation should create synergies with Regulation (EU) 2019/881. In order to facilitate the assessment of conformity with the requirements laid down in this Regulation, products with digital elements that are certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 and which has been identified by the Commission in an implementing act, shall be presumed to be in compliance with the essential requirements of this Regulation in so far as the cybersecurity certificate or statement of conformity or parts thereof cover those requirements. The need for new European cybersecurity certification schemes for products with digital elements should be

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<sup>24</sup> Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

assessed in the light of this Regulation. Such future European cybersecurity certification schemes covering products with digital elements should take into account the essential requirements **and conformity assessment procedures** as set out in this Regulation and facilitate compliance with this Regulation. **For European cybersecurity certification schemes that enter into force before the entry into force of this Regulation, further specifications by means of implementing acts may be needed on detailed aspects of how a presumption of conformity can apply.** The Commission should be empowered to specify, by means of implementing acts, **under which conditions** the European cybersecurity certification schemes ~~that~~ can be used to demonstrate conformity with the essential requirements set out in this Regulation. ~~Furthermore, in order to avoid undue administrative burden for manufacturers, where applicable, the Commission should specify if a cybersecurity certificate issued under such European cybersecurity certification schemes eliminates the obligation for manufacturers to carry out a third-party conformity assessment as provided by this Regulation for corresponding requirements.~~

- (40) Upon entry into force of the implementing act setting out the [Commission Implementing Regulation (EU) No .../... of XXX on the European Common Criteria-based cybersecurity certification scheme] (EUCC) which concerns **hardware** products covered by this Regulation, such as hardware security modules and microprocessors, the Commission may specify, by means of an implementing act, how the EUCC provides a presumption of conformity with the essential requirements as referred to in Annex I of this Regulation or parts thereof. Furthermore, such implementing act may specify how a certificate issued under the EUCC eliminates the obligation for manufacturers to carry out a third-party assessment as requested by this Regulation for corresponding requirements.
- (41) **The current EU standardisation framework which is based on the New Approach principles set out in Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards and on Regulation (EU) No 1025/2012 represents the framework by default to elaborate standards that provide for a presumption of conformity with the relevant essential requirements of this Regulation. European standards should be market-driven, take into account the public interest, as well as the policy objectives clearly stated in the Commission's request to one or more European standardisation organisations to draft harmonised standards, within a set deadline and be based on consensus. However, ~~Where no~~ in the absence of relevant references to harmonised standards, ~~are adopted or where the harmonised standards do not sufficiently address the essential requirements of this Regulation,~~ the Commission should be able to adopt common specifications by means of implementing acts: **establishing** ~~Reasons for developing such common specifications, instead of relying on harmonised standards, might include a refusal of the standardisation request by any of the European standardisation organisations, undue delays in the establishment of appropriate harmonised standards, or a lack of compliance of developed standards with the requirements of this Regulation or with a request of the Commission.~~ **for the essential cybersecurity requirements of this Regulation, provided that in doing so it duly respects the role and functions of standardisation organisations, as an exceptional fall back solution to facilitate the manufacturer's obligation to comply with those cybersecurity requirements, when the standardisation process is blocked or when there are delays in the establishment of appropriate harmonised standards. If such delay is due to the technical complexity of the standard in question, this should be considered by the Commission before contemplating the establishment of common specifications.****
- (41a) **With a view to establishing, in the most efficient way, common specifications that cover the essential requirements of this Regulation, the Commission should involve relevant stakeholders in the process.**

- (41b) Reasonable period should mean, in relation to the publication of reference to harmonised standards in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, a period during which the publication in the Official Journal of the European Union of the reference to the standard, its corrigendum or its amendment is expected and which should not exceed one year after the deadline for drafting a European standard set in accordance with Regulation (EU) No 1025/2012.**
- (41c) In order to facilitate assessment of conformity with the essential requirements laid down by this Regulation, there should be a presumption of conformity for products with digital elements that are in conformity with the common specifications adopted by the Commission according to this Regulation for the purpose of expressing detailed technical specifications of those requirements.
- (42) Manufacturers should draw up an EU declaration of conformity to provide information required under this Regulation on the conformity of products with digital elements with the essential requirements of this Regulation and, where applicable, of the other relevant Union harmonisation legislation by which the product is covered. Manufacturers may also be required to draw up an EU declaration of conformity by other Union legislation. To ensure effective access to information for market surveillance purposes, a single EU declaration of conformity should be drawn up in respect of compliance with all relevant Union acts. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.
- (43) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008 of the European Parliament and of the Council<sup>25</sup>. Rules governing the affixing of the CE marking on products with digital elements should be laid down in this Regulation. The CE marking should be the only marking which guarantees that products with digital elements comply with the requirements of this Regulation.
- (44) In order to allow economic operators to demonstrate conformity with the essential requirements laid down in this Regulation and to allow market surveillance authorities to ensure that products with digital elements made available on the market comply with these requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC of the European Parliament and of the Council<sup>26</sup> establishes modules for conformity assessment procedures in proportion to the level of risk involved and the level of security required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures adequate for verifying the conformity of products with digital elements with the essential requirements set out in this Regulation have been based on those modules. The conformity assessment procedures should examine and verify both product and process-related requirements covering the whole life cycle of products with digital elements, including planning, design, development or production, testing and maintenance of the product.

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<sup>25</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

<sup>26</sup> Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

- (45) ~~As a general rule the eConformity assessment of products with digital elements~~ **that are not covered by Annex III or IIIa of this Regulation should** can be carried out by the manufacturer under its own responsibility following the **internal control** procedure based on Module A of Decision 768/2008/EC as set out in **Annex VI of this Regulation. This also applies to cases where a manufacturer chooses to not apply in whole or in part an applicable harmonised standard, common specification or European cybersecurity certification.** The manufacturer ~~should~~ retains flexibility to choose a stricter conformity assessment procedure involving a third-party. **Under the internal control conformity assessment procedure, the manufacturer ensures and declares on its sole responsibility that the product with digital elements meets all the essential requirements set out in Section 1 of Annex I of this Regulation and that the processes of the manufacturer meet the essential requirements set out in Section 2 of Annex I of this Regulation.** If the product is ~~classified as a critical product~~ belongs to of class I, additional assurance is required to demonstrate conformity with the essential requirements set out in this Regulation. The manufacturer should apply harmonised standards, common specifications or cybersecurity certification schemes under Regulation (EU) 2019/881 which have been identified by the Commission in an implementing act, if it wants to carry out the conformity assessment under its own responsibility (module A). If the manufacturer does not apply such harmonised standards, common specifications or **European** cybersecurity certification schemes, the manufacturer should undergo conformity assessment involving a third party **(based on Modules B and C or H)**. Taking into account the administrative burden on manufacturers and the fact that cybersecurity plays an important role in the design and development phase of tangible and intangible products with digital elements, conformity assessment procedures respectively based on modules B+C or module H of Decision 768/2008/EC have been chosen as most appropriate for assessing the compliance of ~~critical~~ products with digital elements **belonging to a category referred to in Annex III**, in a proportionate and effective manner. The manufacturer that carries out the third-party conformity assessment can choose the procedure that suits best its design and production process. Given the even greater cybersecurity risk linked with the use of ~~products classified as critical~~ class II products, the conformity assessment should always involve a third party, **even where the product complies fully or partly with harmonised standards, common specifications or European cybersecurity certification.**
- (46) While the creation of tangible products with digital elements usually requires manufacturers to make substantial efforts throughout the design, development and production phases, the creation of products with digital elements in the form of software almost exclusively focuses on design and development, while the production phase plays a minor role. Nonetheless, in many cases software products still need to be compiled, built, packaged, made available for download or copied onto physical media before being placed on the market. These activities should be considered as activities amounting to production when applying the relevant conformity assessment modules to verify the compliance of the product with the essential requirements of this Regulation across the design, development and production phases.

**(NEW on Reducing regulatory burden – corresponding to Article 2324a)**

**In relation to small and micro enterprises, in order to ensure proportionality, it is appropriate to alleviate administrative costs without affecting the level of cybersecurity protection of products with digital elements under the scope of this Regulation or the level playing field among manufacturers. Therefore, market surveillance authorities should accept any equivalent documentation meeting the same objectives as the technical documentation requested by this Regulation. Therefore, it is appropriate for the Commission to establish a simplified technical documentation form targeted at the needs of small and micro enterprises.**

**(NEW RECITAL on Member States actions)**

**In order to promote and protect innovation, it is important that the interests of SME manufactures, in particular small and micro enterprises, including start-ups, are taken into particular account. To this objective, Member States ~~cs~~hould develop initiatives which are targeted at small and micro manufacturers, including on training, awareness raising, information communication and on testing and third-party conformity assessment activities. ~~Moreover, the specific interests and needs of SMEs should be taken into account when notified bodies set conformity assessment fees.~~ Translation costs related to mandatory documentation, such as the technical documentation and the information and instructions for the user as required by this Regulation, and communication with authorities may constitute a significant cost for manufacturers, notably those of a smaller scale. ~~Therefore,~~ Member States ~~sh~~ould ~~may~~ consider ~~ensuring~~ that one of the languages determined and accepted by them for relevant manufacturers' documentation and for communication with manufacturer is one which is broadly understood by the largest possible number of users ~~across the internal market.~~**

**(NEW RECITAL on funding)**

**In order to minimise the risks to implementation resulting from lack of knowledge and expertise in the market, as well as in order to facilitate compliance of manufacturers, notably small and micro enterprises, with their obligations laid down in this Regulation, relevant EU funding programmes, as well as the European Cybersecurity Competence Center and National Coordination Centres and the European Digital Innovation Hubs established by the Commission and the Member States at national or EU level may contribute to the implementation of this Regulation. Within their respective mission and fields of competence, they may provide technical and scientific support to small and micro manufacturers, such as for testing activities and third-party conformity assessment. They can also foster the deployment of tools to facilitate the implementation of this Regulation.**

**NEW recital on third-party conformity assessment for micro and small**

**Considering the costs that third-party conformity assessment may entail, funding initiatives at Union level that seek to allievate such costs for micro and small enterprises should be considered.**

**(NEW Recital on guidance by Commission)**

**The Commission should actively support the Member States and economic operators in the implementation and enforcement of this Regulation. Guidance and standardised templates can reduce costs related to familiarisation with this Regulation and related to legal uncertainty especially for smaller companies. Such documents should be developed on particular topics aiming at facilitating the application of this Regulation, while paying particular attention to the needs of small and micro enterprises. The Commission should facilitate the development of such documents and ensure the consultation of relevant stakeholders. Similarly, market surveillance authorities may also consider providing guidance and advice to economic operators on the implementation of the Regulation, paying particular attention to micro and small**

enterprises. In doing so, they should coordinate as appropriate through the ADCO to ensure a consistent implementation of this Regulation.

**(NEW Recital on definition of Micro, small and medium-sized enterprises)**

**Micro, small and medium-sized enterprises or ‘SMEs’ referred to in this Regulation mean micro, small and medium-sized enterprises as defined in the Annex to Recommendation 2003/361/EC. When determining the category an enterprise falls into, the provisions of that Annex should be applied in their entirety. Therefore, when calculating the staff headcount and financial ceilings determining the enterprise categories, the provisions of Article 6 of the Annex to Recommendation 2003/361/EC on establishing the data of an enterprise in consideration of specific types of enterprises, such as partner enterprises or linked enterprises, should also apply.**

- (47) In order to carry out third-party conformity assessment for products with digital elements, conformity assessment bodies should be notified by the national notifying authorities to the Commission and the other Member States, provided they are compliant with a set of requirements, notably on independence, competence and absence of conflicts of interests.
- (48) In order to ensure a consistent level of quality in the performance of conformity assessment of products with digital elements, it is also necessary to lay down requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies. The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (48a) Conformity assessment bodies that have been accredited and notified under Union legislation laying down similar requirements, such as a conformity assessment body that has been notified for a European cybersecurity certification scheme adopted as per Regulation (EU) 2019/881 or notified under the Delegated Regulation (EU) 2022/30, should be newly assessed and notified under this Regulation. However, synergies can be defined by relevant authorities regarding any overlapping requirements in order to prevent an unnecessary financial and administrative burden and ensure a smooth and timely notification process.**
- (49) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (50) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the product with digital elements to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks.



- (51) The notification of a conformity assessment body should be sent by the notifying authority to the Commission and the other Member States via the New Approach Notified and Designated Organisations (NANDO) information system. NANDO is the electronic notification tool developed and managed by the Commission where a list of all notified bodies can be found.
- (52) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (53) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burden for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That should be best achieved through appropriate coordination and cooperation between notified bodies.
- (54) Market surveillance is an essential instrument in ensuring the proper and uniform application of Union legislation. It is therefore appropriate to put in place a legal framework within which market surveillance can be carried out in an appropriate manner. Rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EU) 2019/1020 of the European Parliament and of the Council<sup>27</sup> apply to products with digital elements covered by this Regulation.
- (55) In accordance with Regulation (EU) 2019/1020, market surveillance authorities carry out market surveillance in the territory of that Member State. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks. Each Member State should designate one or more market surveillance authorities in its territory. Member States may choose to designate any existing or new authority to act as market surveillance authority, including ~~national~~ competent authorities ~~referred to in established pursuant to~~ Article 8 ~~[Article X]~~ of ~~Directive [Directive (EU) 2022/2555XXX/XXXX (NIS2)]~~ or designated national cybersecurity certification authorities referred to in Article 58 of Regulation (EU) 2019/881 **or market surveillance authorities designated for the purpose of Directive 2014/53/EU**. Economic operators should fully cooperate with market surveillance authorities and other competent authorities. Each Member State should inform the Commission and the other Member States of its market surveillance authorities and the areas of competence of each of those authorities and should ensure the necessary resources and skills to carry out the surveillance tasks relating to this Regulation. As per Article 10(2) and (3) of Regulation (EU) 2019/1020, each Member State should appoint a single liaison office that should be responsible, among others, for representing the coordinated position of the market surveillance authorities and assisting in the cooperation between market surveillance authorities in different Member States.
- (56) A dedicated administrative cooperation group (ADCO) should be established for the uniform application of this Regulation, pursuant to Article 30(2) of Regulation (EU)

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<sup>27</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1).

2019/1020. This ADCO should be composed of representatives of the designated market surveillance authorities and, if appropriate, representatives of the single liaison offices. The Commission should support and encourage cooperation between market surveillance authorities through the Union Product Compliance Network, established on the basis of Article 29 of Regulation (EU) 2019/1020 and comprising representatives from each Member State, including a representative of each single liaison office referred to in Article 10 of Regulation (EU) 2019/1020 and an optional national expert, the chairs of ADCOs, and representatives from the Commission. The Commission should participate in the meetings of the Network, its sub-groups and this respective ADCO. It should also assist this ADCO by means of an executive secretariat that provides technical and logistic support. **ADCO may also invite independent experts to participate, and liaise with other ADCOs, such as the one established under Directive 2014/53/EU.**

- (57) In order to ensure timely, proportionate and effective measures in relation to products with digital elements presenting a significant cybersecurity risk, a Union safeguard procedure should be foreseen under which interested parties are informed of measures intended to be taken with regard to such products. This should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage where necessary. Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (58) In certain cases, a product with digital elements which complies with this Regulation, may nonetheless present a significant cybersecurity risk or pose a risk to the health or safety of persons, to compliance with obligations under Union or national law intended to protect fundamental rights, the availability, authenticity, integrity or confidentiality of services offered using an electronic information system by ~~essential~~ entities of ~~a~~ the type referred to in ~~{Annex I to Directive (EU) 2022/2555XXX/XXXX (NIS2)}~~ or to other aspects of public interest protection. Therefore it is necessary to establish rules which ensure mitigation of those risks. As a result, market surveillance authorities should take measures to require the economic operator to ensure that the product no longer presents that risk, to recall it or to withdraw it, depending on the risk. As soon as a market surveillance authority restricts or forbids the free movement of a product in such way, the Member State should notify without delay the Commission and the other Member States of the provisional measures, indicating the reasons and justification for the decision. Where a market surveillance authority adopts such measures against products presenting a risk, the Commission should enter into consultation with the Member States and the relevant economic operator or operators without delay and should evaluate the national measure. On the basis of the results of this evaluation, the Commission should decide whether the national measure is justified or not. The Commission should address its decision to all Member States and immediately communicate it to them and the relevant economic operator or operators. If the measure is considered justified, the Commission may also consider adopting proposals to revise the respective Union legislation.
- (59) For products with digital elements presenting a significant cybersecurity risk, and where there is reason to believe that these are not compliant with this Regulation, or for products that are compliant with this Regulation, but that present other important risks, such as risks to the health or safety of persons, fundamental rights or the provision of the services by ~~essential~~ entities of ~~a~~ the type referred to in ~~{Annex I to Directive (EU) 2022/2555XXX/XXXX (NIS2)}~~, the Commission may request ENISA to carry out an evaluation. Based on that evaluation, the Commission may adopt, through implementing acts, corrective or restrictive measures at Union level, including ordering withdrawal from the market, or recalling of the respective products, within a reasonable period, commensurate with the

nature of the risk. The Commission may have recourse to such intervention only in exceptional circumstances that justify an immediate intervention to preserve the good functioning of the internal market, and only where no effective measures have been taken by surveillance authorities to remedy the situation. Such exceptional circumstances may be emergency situations where, for example, a non-compliant product is widely made available by the manufacturer throughout several Member States, used also in key sectors by entities under the scope of ~~{Directive (EU) 2022/2555XXX / XXXX (NIS2)}~~, while containing known vulnerabilities that are being exploited by malicious actors and for which the manufacturer does not provide available patches. The Commission may intervene in such emergency situations only for the duration of the exceptional circumstances and if the non-compliance with this Regulation or the important risks presented persist.

- (60) In cases where there are indications of non-compliance with this Regulation in several Member States, market surveillance authorities should be able to carry out joint activities with other authorities, with a view to verifying compliance and identifying cybersecurity risks of products with digital elements.
- (61) Simultaneous coordinated control actions ('sweeps') are specific enforcement actions by market surveillance authorities that can further enhance product security. Sweeps should, in particular, be conducted where market trends, consumer complaints or other indications suggest that certain product categories are often found to present cybersecurity risks. ENISA should submit proposals for categories of products for which sweeps could be organised to the market surveillance authorities, based, among others, on the information notifications it receives of in relation to product actively exploited product vulnerabilities and incidents having an impact on the security of the product with digital elements it receives.
- (62) In order to ensure that the regulatory framework can be adapted where necessary, the power to adopt acts in accordance with Article 290 of the Treaty **on the Functioning of the European Union** should be delegated to the Commission in respect of updates to the lists of **critical categories of products with digital elements** in Annexes III and IIIa ~~specifying the definitions of the these product categories. Power to adopt acts in accordance with that Article should be delegated to the Commission to identify products with digital elements covered by other Union rules which achieve the same level of protection as this Regulation, specifying whether a limitation or exclusion from the scope of this Regulation would be necessary as well as the scope of that limitation, if applicable.~~ Power to adopt acts in accordance with that Article should also be delegated to the Commission in respect of the potential mandating of certification of certain highly critical products with digital elements based on criticality criteria set out in this Regulation **and an impact assessment**, as well as for specifying the minimum content of the EU declaration of conformity and supplementing the elements to be included in the technical documentation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making<sup>28</sup>. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

- (63) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to: **specify the definitions of the categories of products with digital elements listed in Annexes III and IIIa**, specify the format and elements of the software bill of materials, specify further the type of information, format and procedure of the notifications on actively exploited vulnerabilities and incidents **having an impact on the security of products with digital elements** submitted to ENISA by the manufacturers, **establish common specifications covering technical requirements that provide a means to comply with the essential requirements set out in Annex I**, specify the European cybersecurity certification schemes adopted pursuant to Regulation (EU) 2019/881 that can be used to demonstrate conformity with the essential requirements or parts thereof ~~fore~~ as set out in Annex I ~~of to~~ this Regulation **and related conformity assessment procedures**, ~~adopt common specifications in respect of the essential requirements set out in Annex I~~, lay down technical specifications for pictograms or any other marks related to the security of the products with digital elements, and mechanisms to promote their use, decide on corrective or restrictive measures at Union level in exceptional circumstances which justify an immediate intervention to preserve the good functioning of the internal market. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>29</sup>.
- (64) In order to ensure trustful and constructive cooperation of market surveillance authorities at Union and national level, all parties involved in the application of this Regulation should respect the confidentiality of information and data obtained in carrying out their tasks.
- (65) In order to ensure effective enforcement of the obligations laid down in this Regulation, each market surveillance authority should have the power to impose or request the imposition of administrative fines. Maximum levels for administrative fines to be provided for in national laws for non-compliance with the obligations laid down in this Regulation should therefore be established. When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation should be taken into account and as a minimum those explicitly established in this Regulation, including whether administrative fines have been already applied by other market surveillance authorities to the same operator for similar infringements. Such circumstances can be either aggravating, in situations where the infringement by the same operator persists on the territory of other Member States than the one where an administrative fine has already been applied, or mitigating, in ensuring that any other administrative fine considered by another market surveillance authority for the same economic operator or the same type of breach should already take account, along with other relevant specific circumstances, of a penalty and the quantum thereof imposed in other Member States. In all such cases, the cumulative administrative fine that could be applied by market surveillance authorities of several Member States to the same economic operator for the same type of infringement should ensure the respect of the principle of proportionality.
- (66) Where administrative fines are imposed on persons that are not an undertaking, the competent authority should take account of the general level of income in the Member State as well as the economic situation of the person when considering the appropriate amount of the fine. It should be for the Member States to determine whether and to what extent public authorities should be subject to administrative fines.

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<sup>29</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13).

- (67) In its relationships with third countries, the EU endeavours to promote international trade in regulated products. A broad variety of measures can be applied in order to facilitate trade, including several legal instruments such as bilateral (inter-governmental) Mutual Recognition Agreements (MRAs) for conformity assessment and marking of regulated products. MRAs are established between the Union and third countries, which are on a comparable level of technical development and have a compatible approach concerning conformity assessment. These agreements are based on the mutual acceptance of certificates, marks of conformity and test reports issued by the conformity assessment bodies of either party in conformity with the legislation of the other party. Currently MRAs are in place for several countries. The agreements are concluded in a number of specific sectors, which might vary from one country to another. In order to further facilitate trade, and recognising that supply chains of products with digital elements are global, MRAs concerning conformity assessment may be concluded for products regulated under this Regulation by the Union in accordance with Article 218 TFEU. Cooperation with partner countries is also important, in order to strengthen cyber resilience globally, as in the long term this will contribute to a strengthened cybersecurity framework both within and outside of the EU.

(new recital:)

**Consumers should be entitled to enforce their rights in relation to the obligations imposed on economic operators under this Regulation through representative actions in accordance with Directive (EU) 2020/1828 of the European Parliament and of the Council<sup>30</sup>. For that purpose, this Regulation should provide that Directive (EU) 2020/1828 is applicable to the representative actions concerning infringements of this Regulation that harm or can harm the collective interests of consumers. Annex I to that Directive should therefore be amended accordingly. It is for the Member States to ensure that that amendment is reflected in their transposition measures adopted in accordance with that Directive, although the adoption of national transposition measures in that regard is not a condition for the applicability of that Directive to those representative actions. The applicability of that Directive to the representative actions brought against infringements by economic operators of provisions of this Regulation that harm or can harm the collective interests of consumers should start from the date of application of this Regulation.**

- (68) The Commission should periodically review this Regulation, in consultation with interested parties, in particular with a view to determining the need for modification in the light of changes to societal, political, technological or market conditions.
- (69) Economic operators should be provided with a sufficient time to adapt to the requirements of this Regulation. This Regulation should apply [~~24~~ **36** months] from its entry into force, with the exception of the reporting obligations concerning actively exploited vulnerabilities and incidents **having an impact on the security of products with digital elements**, which should apply [~~12~~ **24** months] from the entry into force of this Regulation.
- (70) Since the objective of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of the effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of

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<sup>30</sup> Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC (OJ L 409, 4.12.2020, p. 1).

proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

- (71) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 of the European Parliament and of the Council<sup>31</sup> and delivered ~~its~~**an** opinion on **9 November 2022**<sup>32</sup>,

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<sup>31</sup> Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

<sup>32</sup> **OJ C 452, 29.11.2022, p. 23.**

HAVE ADOPTED THIS REGULATION:

## CHAPTER I

### GENERAL PROVISIONS

#### *Article 1*

##### *Subject matter*

This Regulation lays down:

- (a) rules for the ~~placing on~~ **making available on** the market of products with digital elements to ensure the cybersecurity of such products;
- (b) essential requirements for the design, development and production of products with digital elements, and obligations for economic operators in relation to these products with respect to cybersecurity;
- (c) essential requirements for the vulnerability handling processes put in place by manufacturers to ensure the cybersecurity of products with digital elements during the whole life cycle, and obligations for economic operators in relation to these processes;
- (d) rules on market surveillance and enforcement of the above-mentioned rules and requirements.

#### *Article 2*

##### *Scope*

1. This Regulation applies to products with digital elements whose intended or reasonably foreseeable use includes a direct or indirect logical or physical data connection to a device or network.
2. This Regulation does not apply to products with digital elements to which the following Union acts apply:
  - (a) Regulation (EU) 2017/745;
  - (b) Regulation (EU) 2017/746;
  - (c) Regulation (EU) 2019/2144.
3. This Regulation does not apply to products with digital elements that have been certified in accordance with Regulation (EU) 2018/1139.
- 3a. This Regulation does not apply to equipment that falls within the scope of Directive 2014/90/EU of the European Parliament and of the Council<sup>33</sup>.**
4. The application of this Regulation to products with digital elements covered by other Union rules laying down requirements that address all or some of the risks covered by the essential requirements set out in Annex I may be limited or excluded, where:
  - (a) such limitation or exclusion is consistent with the overall regulatory framework applying to those products; and

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<sup>33</sup> **Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146).**

- (b) the sectoral rules achieve the same **or a higher** level of protection as the one provided for by this Regulation.

~~The Commission is empowered to adopt delegated acts in accordance with Article 50 to amend this Regulation specifying whether such limitation or exclusion is necessary, the concerned products and rules, as well as the scope of the limitation, if relevant.~~

**4a. This Regulation does not apply to components that are exclusively manufactured as spare parts to replace identical components and are supplied by the manufacturer of the original product with digital elements.**

5. This Regulation does not apply to products with digital elements developed **or modified** exclusively for national security, **public security, defence** or military purposes or to products specifically designed to process classified information.

*Article 3*

*Definitions*

For the purposes of this Regulation, the following definitions apply:

- (1) ‘product with digital elements’ means any software or hardware product **and including** its remote data processing solutions, **including and** software or hardware components to be placed on the market separately;
- (2) ‘remote data processing’ means any data processing at a distance for which the software **or hardware** is designed and developed by the manufacturer or under the responsibility of the manufacturer, and the absence of which would prevent the product with digital elements from performing one of its functions;
- ~~(3) ‘critical product with digital elements’ means a product with digital elements that presents a cybersecurity risk in accordance with the criteria laid down in Article 6(2) and whose core functionality is set out in Annex III;~~
- ~~(4) ‘highly critical product with digital elements’ means a product with digital elements that presents a cybersecurity risk in accordance with the criteria laid down in Article 6(5);<sup>34</sup>~~
- (4) ‘operational technology’ means programmable digital systems or devices that interact with the physical environment or manage devices that interact with the physical environment;
- (5) ‘software’ means the part of an electronic information system which consists of computer code;
- (6) ‘hardware’ means a physical electronic information system, or parts thereof capable of processing, storing or transmitting of digital data;

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<sup>34</sup> Definition not necessary since highly critical is defined in Article 6a and in recitals.



- (7) 'component' means software or hardware intended for integration into an electronic information system;
- (8) 'electronic information system' means any system, including electrical or electronic equipment, capable of processing, storing or transmitting digital data;
- (9) 'logical connection' means a virtual representation of a data connection implemented through a software interface;
- (10) 'physical connection' means any connection between electronic information systems or components implemented using physical means, including through electrical, **optical** or mechanical interfaces, wires or radio waves;
- (11) 'indirect connection' means a connection to a device or network, which does not take place directly but rather as part of a larger system that is directly connectable to such device or network;
- (12) 'privilege' means an access right granted to particular users or programmes to perform security-relevant operations within an electronic information system;
- (13) 'elevated privilege' means an access right granted to particular users or programmes to perform an extended set of security-relevant operations within an electronic information system that, if misused or compromised, could allow a malicious actor to gain wider access to the resources of a system or organisation;
- (14) 'endpoint' means any device that is connected to a network and serves as an entry point to that network;
- (15) 'networking or computing resources' means data or hardware or software functionality that is accessible either locally or through a network or another connected device;
- (16) 'economic operator' means the manufacturer, the authorised representative, the importer, the distributor, or any other natural or legal person who is subject to obligations **in relation to the manufacture of products or making them available on the market in accordance with ~~laid down~~ by** this Regulation;
- (17) 'manufacturer' means any natural or legal person who develops or manufactures products with digital elements or has products with digital elements designed, developed or manufactured, and markets them under his or her name or trademark, whether for payment or free of charge;
- (18) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his or her behalf in relation to specified tasks;
- (19) 'importer' means any natural or legal person established in the Union who places on the market a product with digital elements that bears the name or trademark of a natural or legal person established outside the Union;
- (20) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a product with digital elements available on the Union market without affecting its properties;

- (21) 'placing on the market' means the first making available of a product with digital elements on the Union market;
- (22) 'making available on the market' means any supply of a product with digital elements for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (23) 'intended purpose' means the use for which a product with digital elements is intended by the manufacturer, including the specific context and conditions of use, as specified in the information supplied by the manufacturer in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;
- (24) 'reasonably foreseeable use' means use that is not necessarily the intended purpose supplied by the manufacturer in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation, but which is likely to result from reasonably foreseeable human behaviour or technical operations or interactions;
- (25) 'reasonably foreseeable misuse' means the use of a product with digital elements in a way that is not in accordance with its intended purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;
- (26) 'notifying authority' means the national authority responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for their monitoring;
- (27) 'conformity assessment' means the process of verifying whether the essential requirements set out in Annex I have been fulfilled;
- (28) 'conformity assessment body' means a **conformity assessment** body as defined in Article 2, **point** (13), of Regulation (EU) No 765/2008;
- (29) 'notified body' means a conformity assessment body designated in accordance with Article 33 of this Regulation and other relevant Union harmonisation legislation;
- (30) 'substantial modification' means a change to the product with digital elements following its placing on the market, which affects the compliance of the product with digital elements with the essential requirements set out in Section 1 of Annex I or results in a modification to the intended ~~use~~ **purpose** for which the product with digital elements has been assessed;
- (32) 'CE marking' means a marking by which a manufacturer indicates that a product with digital elements and the processes put in place by the manufacturer are in conformity with the essential requirements set out in Annex I and other applicable Union **harmonisation** legislation ~~harmonising the conditions for the marketing of products ('Union harmonisation legislation')~~ providing for its affixing;
- (32a) '**Union harmonisation legislation**' means **Union legislation listed in Annex I to Regulation (EU) 2019/1020 and any other Union legislation harmonising the conditions for the marketing of products to which that Regulation applies;**

- (33) ‘market surveillance authority’ means ~~the~~ **a market surveillance** authority as defined in Article 3, point (4), of Regulation (EU) 2019/1020;
- (34) ‘harmonised standard’ means a harmonised standard as defined in Article 2, point (1)(c), of Regulation (EU) No 1025/2012;
- (35) ‘cybersecurity risk’ means risk as defined in Article ~~62~~, **point (9)**, ~~[Article X]~~ of Directive (EU) ~~2022/2555~~ ~~[Directive XXX/XXXX (NIS2)]~~;
- (36) ‘significant cybersecurity risk’ means a cybersecurity risk which, based on its technical characteristics, can be assumed to have a high likelihood of an incident that could lead to a severe negative impact, including by causing considerable material or non-material loss or disruption;
- (37) ‘software bill of materials’ means a formal record containing details and supply chain relationships of components included in the software elements of a product with digital elements;
- (38) ‘vulnerability’ means a vulnerability as defined in Article ~~62~~, **point (15)**, ~~[Article X]~~ of Directive (EU) ~~2022/2555~~ ~~[Directive XXX/XXXX (NIS2)]~~;
- (38a) **‘exploitable vulnerability’ means a vulnerability as defined in Article 6, point (15), of Directive (EU) 2022/2555 that has the potential to be effectively used by an adversary under practical operational conditions;**
- (39) ‘actively exploited vulnerability’ means a vulnerability **as defined in Article 6, point (15), of Directive (EU) 2022/2555** for which there is reliable evidence that ~~execution of a malicious actor has code was performed by an actor on attempted to exploit it in a system without permission of the system owner, irrespective of whether this attempt has been successful or not and which has either been attempted or has been successful;~~
- (40) ‘personal data’ means **personal** data as defined in Article 4, **point (1)**, of Regulation (EU) 2016/679.
- (41) ‘recall’ means recall as defined in Article 3, point (22), of Regulation (EU) 2019/1020;
- (42) ‘withdrawal’ means withdrawal as defined in Article 3, point (23), of Regulation (EU) 2019/1020.
- (43) **‘incident having an impact on the security of the product with digital elements’ means an incident as defined in Article 6, point (6), of Directive (EU) 2022/2555 which negatively affects the ability of a manufacturer’s product with digital elements to protect the availability, authenticity, integrity or confidentiality of data or functions.**
- (44) ‘micro, small and medium-sized enterprises’ or ‘SMEs’ means micro, small and medium-sized enterprises as defined in the Annex to Recommendation 2003/361/EC;
- (45) ‘cybersecurity’ means cybersecurity as defined in Article 2, point (1), of Regulation (EU) 2019/881.

## *Article 4*

### *Free movement*

1. Member States shall not impede, for the matters covered by this Regulation, the making available on the market of products with digital elements which comply with this Regulation.
- 1(a) **In accordance with paragraph 1, this Regulation shall not prevent Member States from subjecting products with digital elements to additional cybersecurity requirements for the procurement or use of those products for specific purposes, provided that such requirements are consistent with Member States' obligations laid down in Union law.**
2. At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the presentation and use of a product with digital elements which does not comply with this Regulation.
3. Member States shall not prevent the making available of unfinished software which does not comply with this Regulation provided that the software is only made available for a limited period required for testing purposes and that a visible sign clearly indicates that it does not comply with this Regulation and will not be available on the market for purposes other than testing.
4. **Paragraph 3 does not apply to safety components as specified under other Union harmonisation legislation.**
5. **This Regulation shall not prevent Member States from subjecting products with digital elements to additional measures when these products will be used for military, defence or national security purposes, and such measures are necessary and proportionate for the achievement of those purposes.**
6. **The obligations laid down in this Regulation shall not entail the supply of information the disclosure of which would be contrary to the essential interests of Member States' national security, public security or defence.**

## *Article 5*

### *Requirements for products with digital elements*

Products with digital elements shall only be made available on the market where:

- (1) they meet the essential requirements set out in Section 1 of Annex I, under the condition that they are properly installed, maintained, used for their intended purpose or under conditions which can reasonably be foreseen, and, where applicable, updated, and
- (2) the processes put in place by the manufacturer comply with the essential requirements set out in Section 2 of Annex I.

## Article 6

### *Critical Classification of products with digital elements subject to specific conformity assessment procedures*

1. ~~Products with digital elements that belong to a category which is listed in Annex III shall be considered critical products with digital elements. Products with digital elements~~ which have the core functionality of a category that is listed in Annex III to this Regulation shall **be subject to the conformity assessment procedures referred to in Article 24 (2) and (3).** ~~be considered as falling in belonging to that category.~~
- 1a. ~~The~~ **categories of critical products with digital elements referred to in paragraph 1 shall be** ~~are~~ divided into class I and class II as set out in Annex III, ~~reflecting the level of cybersecurity risk related to these products.~~ **The categories of products with digital elements listed in class I of Annex III meet one of the following criteria:**
  - (a) ~~the cybersecurity related functionality of the product with digital elements~~ **has a cybersecurity-related functionality, and in particular performs primarily functions critical to the cybersecurity of other products, networks or services, including securing authentication and access, intrusion prevention and detection, endpoint security or network protection;**
  - (b) ~~the product with digital elements performs a central system function, such as network management, configuration control, virtualisation, processing of personal data, or a function which carries a significant risk of adverse effects in terms of its intensity and ability having the potential to disrupt, control or cause damage to a large number of other products with digital elements through direct manipulation, such as a central system function, such as including network management, configuration control, virtualisation, processing of personal data~~

The categories of products with digital elements listed in class II of Annex III meet both criteria referred to in points (a) and (b) of this paragraph.

2. [The Commission is empowered to adopt delegated acts in accordance with Article 50 to amend Annex III by including in the list **within each class** of the categories of **critical** products with digital elements a new category **and specifying its definition**, moving a **category of products from one class to the other** or withdrawing an existing one from that list. When assessing the need to amend the list in Annex III, the Commission shall take into account the **cybersecurity-related functionalities or the level function and the level of cybersecurity risk posed by** ~~of cybersecurity risk related to the category of the~~ products with digital elements **as set out by the criteria referred to in paragraph 2 1a.** ~~In determining the level of cybersecurity risk, one or several of the following criteria shall be taken into account.:~~
  - (a) ~~the cybersecurity related functionality of the product with digital elements, and whether the product with digital elements has at least one of following attributes:~~
    - (i) ~~it is designed to run with elevated privilege or manage privileges;~~
    - (ii) ~~it has direct or privileged access to networking or computing resources;~~

- ~~(iii) it is designed to control access to data or operational technology;~~
- ~~(iv) it performs a function critical to trust, in particular security functions such as network control, endpoint security, and network protection.~~
- ~~(b) the intended use in sensitive environments, including in industrial settings or by essential entities of the type referred to in the Annex [Annex I] to the Directive [Directive XXX/XXXX (NIS2)];~~
- ~~(c) the intended use of performing critical or sensitive functions, such as processing of personal data;~~
- ~~(d) the potential extent of an adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons;~~
- ~~(e) the extent to which the use of products with digital elements has already caused material or non-material loss or disruption or has given rise to significant concerns in relation to the materialisation of an adverse impact.]~~

**3.** ~~[By ... [18 months after the date of entry into force of this Regulation], t~~The Commission is ~~empowered to~~ **shall** adopt an ~~delegated~~ **implementing** act in accordance with Article 50 to supplement this Regulation by specifying the definitions of the ~~product~~ categories of **products with digital elements** under class I and class II as set out in Annex III and the definitions of the categories of products with digital elements set out in Annex IIIa. ~~The delegated act shall be adopted [by 12 months since the entry into force of this Regulation].~~

**That implementing act shall be adopted in accordance with the examination procedure referred to in Article 51(2).]**

**4.** ~~Critical products with digital elements shall be subject to the conformity assessment procedures referred to in Article 24(2) and (3).~~

#### *Article 6a*

##### *Highly critical products with digital elements*

**1.** The Commission is empowered to adopt delegated acts in accordance with Article 50 to supplement this Regulation to determine which products with digital elements that have the core functionality of a category that is listed in Annex IIIa to this Regulation shall be required ~~to obtain a European cybersecurity certificate at the assurance level of ‘substantial’ or ‘high’ under a European cybersecurity certification scheme adopted pursuant to Regulation (EU) 2019/881 to demonstrate conformity with the essential requirements set out in Annex I to this Regulation or parts thereof, provided that a European cybersecurity certification scheme covering those categories of products with digital elements has been adopted pursuant to Regulation (EU) 2019/881, and is available to manufacturers.~~ The delegated acts shall specify the required assurance level, ‘substantial’ or ‘high’, that shall be proportionate to the level of cybersecurity risk associated with the products with digital elements and shall take account of their intended purpose, including their critical dependency by entities of a type referred to in Annex I to Directive (EU) 2022/2555.

**Before adopting such delegated acts and provided that a European cybersecurity certification scheme as referred to in the first subparagraph of this paragraph is available, the Commission shall by ... [18 months after the date of entry into force of this Regulation] carry out an impact assessment analysing the potential market impact of the envisaged measures. The impact assessment shall also take into account the intended purpose of the products with digital elements considered to be subject to such measures, including the extent to which there is a critical dependency on these products of entities of a type referred to in Annex I to Directive (EU) 2022/2555, and include an analysis of the capacity level of the Member States for the implementation of the respective European cybersecurity certification scheme.**

**Where no delegated act as referred to in the first subparagraph has been adopted, products with digital elements which have the core functionality of a category listed in Annex IIIa shall be subject to the conformity assessment procedures referred to in Article 24 (3).**

**The delegated acts referred to in the first subparagraph shall provide for an adequate transition period for their application.**

2. [The Commission is empowered to adopt delegated acts in accordance with Article 50 to **amend Annex IIIa by adding or withdrawing** ~~supplement this Regulation by specifying~~ categories of highly critical products with digital elements ~~for which the manufacturers shall be required to obtain a European cybersecurity certificate under a European cybersecurity certification scheme pursuant to Regulation (EU) 2019/881 to demonstrate conformity with the essential requirements set out in Annex I, or parts thereof.~~ When determining such categories of highly critical products with digital elements **and the required assurance level**, the Commission shall take into account **the criteria referred to in paragraph 2 of Article 6 (1a)** ~~the level of cybersecurity risk related to the category of products with digital elements, in light of one or several of the criteria listed in paragraph 2,~~ as well as in view of the assessment of whether that category of products is **any of the following criteria**:

- (a) ~~used or~~ **the extent to which there is a critical dependency of entities of a type referred to in Annex I to the Directive (EU) 2022/2555 on the category of products with digital elements** ~~relied upon by of the essential entities of a the type referred to in Annex [Annex I] to the Directive (EU) 2022/2555 [Directive XXX/ XXXX (NIS2)] or will have potential future significance for the activities of these entities; or~~

- (b) **relevant for the resilience of the overall the extent to which cybersecurity incidents and exploited vulnerabilities concerning the category of products with digital elements can lead to serious disruptions to critical supply chains of products with digital elements against disruptive events across the internal market.**

**Before adopting such delegated acts, the Commission shall carry out an impact assessment of the type referred to in paragraph 1.**

**The delegated acts referred to in the first subparagraph shall provide for an adequate transition period for their application.**

*Article 7*

*General product safety*

By way of derogation from Article 2(1), third subparagraph, point (b), of Regulation (EU) 2023/988 [~~General Product Safety Regulation~~], **Chapter III, Section 1, Chapters V and VII, and Chapters IX to XI of that Regulation shall apply to products with digital elements with respect to safety risks not covered by this Regulation** where those products with digital elements are not subject to specific requirements laid down in other Union harmonisation legislation **as defined in within the meaning of [Article 3, point (27) of the General Product Safety Regulation (EU) 2023/988], Chapter III, Section 1, Chapters V and VII, and Chapters IX to XI of Regulation [General Product Safety Regulation] shall apply to those products with respect to safety risks not covered by this Regulation.**

## Article 8

### *High-risk AI systems*

1. **Without prejudice to the requirements relating to accuracy and robustness set out in Article [Article 15] Products with digital elements classified as high-risk AI systems in accordance with Article [Article 6] of Regulation [the AI Regulation], products with digital elements which fall within the scope of this Regulation, and which are classified as high-risk AI systems pursuant to Article [Article 6] of Regulation [the AI Regulation] and fulfil the essential requirements set out in Section 1 of Annex I of this Regulation, and where the processes put in place by the manufacturer are compliant with the essential requirements set out in Section 2 of Annex I, shall be deemed in compliance with the cybersecurity requirements related to cybersecurity set out in Article [Article 15] of that Regulation [the AI Regulation], without prejudice to the other requirements related to accuracy and robustness included in the aforementioned Article, and in so far as the achievement of the level of protection required by those requirements is demonstrated by the EU declaration of conformity issued under this Regulation. if:**
  - (a) **they fulfil the essential requirements set out in Section 1 of Annex I to this Regulation;**
  - (b) **the processes put in place by the manufacturer are compliant with the essential requirements set out in Section 2 of Annex I to this Regulation; and**
  - (c) **the achievement of the level of cybersecurity protection required under Article [Article 15] of Regulation [the AI Regulation] is demonstrated in the EU declaration of conformity issued under this Regulation.**
2. For the products **with digital elements** and cybersecurity requirements referred to in paragraph 1, the relevant conformity assessment procedure as required by Article [Article 43 ] of Regulation [AI Regulation] shall apply. For the purpose of that assessment, notified bodies which are ~~entitled~~ **competent** to control the conformity of the high-risk AI systems under the Regulation [AI Regulation] shall be also ~~entitled~~ **competent** to control the conformity of ~~the~~ high-risk AI systems **which fall** within the scope of this Regulation with the requirements set out in Annex I to this Regulation, provided that the compliance of those notified bodies with the requirements laid down in Article 29 of this Regulation ~~have~~ **has** been assessed in the context of the notification procedure under Regulation [AI Regulation].
3. By **way of** derogation from paragraph 2, ~~critical~~ products with digital elements listed in Annex III ~~of to~~ this Regulation, which ~~have to apply~~ **are subject to** the conformity assessment procedures referred to in Articles 24(2)(a), 24(2)(b), 24(3)(a) and 24(3)(b)



~~under~~ of this Regulation and which are also classified as high-risk AI systems ~~according~~ pursuant to Article [Article 6] of ~~the~~ Regulation [AI Regulation], and to which the conformity assessment procedure based on internal control referred to in Annex [Annex VI] to Regulation [the AI Regulation] applies, shall be subject to the conformity assessment procedures as required ~~by~~ ~~under~~ this Regulation in so far as the essential requirements of this Regulation are concerned.

#### *Article 9*

##### *Machinery products*

~~Machinery products under the scope of Regulation [Machinery Regulation proposal] which are products with digital elements within the meaning of this Regulation and for which an EU declaration of conformity has been issued on the basis of this Regulation shall be deemed to be in conformity with the requirements related to cybersecurity regarding the protection against corruption and safety and reliability of control systems essential health and safety requirements set out in Sections 1.1.9 and 1.2.1 of Annex [Annex III, Sections 1.1.9 and 1.2.1] to Regulation [Machinery Regulation proposal], as regards protection against corruption and safety and reliability of control systems, and in so far as if the achievement of the level of cybersecurity protection required by under those requirements Sections is demonstrated in the EU declaration of conformity issued under pursuant to this Regulation.~~

## CHAPTER II

### OBLIGATIONS OF ECONOMIC OPERATORS

#### *Article 10*

##### *Obligations of manufacturers*

1. When placing a product with digital elements on the market, manufacturers shall ensure that it has been designed, developed and produced in accordance with the essential requirements set out in Section 1 of Annex I.
2. For the purposes of complying with the obligation laid down in paragraph 1, manufacturers shall undertake an assessment of the cybersecurity risks associated with a product with digital elements and take the outcome of that assessment into account during the planning, design, development, production, delivery and maintenance phases of the product with digital elements with a view to minimising cybersecurity risks, preventing security incidents and minimising the impacts of such incidents, including in relation to the health and safety of users.
  - 2a. **The risk assessment referred to in paragraph 1 shall be documented and updated as appropriate during the expected lifetime of the product. It shall comprise at least an analysis of cybersecurity risks based on the intended purpose and reasonably foreseeable use, as well as the specific conditions of use of the product with digital elements, such as the operational environment, and the assets to be protected, taking into account the whole life cycle of the product. The risk assessment shall indicate the specific security requirements as set out in point 3 of section 1 of Annex I that are applicable to the respective product with digital elements and how these are implemented as informed by the risk assessment.**
3. When placing a product with digital elements on the market, the manufacturer shall include a cybersecurity risk assessment in the technical documentation as set out in Article 23 and Annex V. For products with digital elements referred to in Articles 8 and 24(4) that are also subject to other Union acts, the cybersecurity risk assessment may be part of the risk assessment required by those respective Union acts. Where certain essential requirements are not applicable to the marketed product with digital elements, the manufacturer shall include a clear justification in that documentation.
4. For the purposes of complying with the obligation laid down in paragraph 1, manufacturers shall exercise due diligence when integrating components sourced from third parties ~~in products with digital elements~~ **in a manner that such components do not compromise the security of the product with digital elements.** ~~They shall ensure that such components do not compromise the security of the product with digital elements.~~
5. The manufacturer shall systematically document, in a manner that is proportionate to the nature and the cybersecurity risks, relevant cybersecurity aspects concerning the product with digital elements, including vulnerabilities ~~they~~ **it** becomes aware of and any relevant information provided by third parties, and, where applicable, update the **cybersecurity** risk assessment of the product.

6. ~~When placing a product with digital elements on the market, and for the expected product lifetime or for a period of five years from the placing of the product on the market, whichever is shorter, Manufacturers shall ensure, when placing a product with digital elements on the market and for a period of time after the placing on the market appropriate to the type of and its for the expected product lifetime, that vulnerabilities of that product, including its components, and components not supplied in the course of a commercial activity integrated in it are handled effectively and in accordance with the essential requirements set out in Section 2 of Annex I.~~

**Manufacturers shall determine the expected product lifetime referred to in the first subparagraph of this paragraph taking into account the following elements:**

- (a) **relevant Union law determining the lifetime of products with digital elements;**
- (b) **the nature of the product with digital elements, including the licensing terms under which it is made available;**
- (c) **the time users reasonably expect to be able to use the product with digital elements given its functionality and intended purpose and therefore can expect to receive security updates;**
- (d) **the expected availability of the operating environment the product with digital elements is intended for;**
- (e) **the lifetime of products with digital elements offering a similar functionality placed on the market by other manufacturers, including, where available, relevant guidance provided by market surveillance authorities;**
- (f) **the lifetime of integrated components that provide core functions and are sourced from third parties.**

**Upon request by a market surveillance authority, manufacturers shall provide a justification of how the expected product lifetime has been determined taking account of the elements in the second subparagraph of this paragraph.**

Manufacturers shall have appropriate policies and procedures, including coordinated vulnerability disclosure policies, referred to in Section 2, point (5), of Annex I, to process and remediate potential vulnerabilities in the product with digital elements reported from internal or external sources.

**Security updates, referred to in Section 2, point (8), of Annex I, which have been made available to users shall remain available for a minimum duration of 10 years.**

6a. **For the purpose of complying with the obligation provided for in the first subparagraph of paragraph 6, where manufacturers have placed subsequent versions of a software product on the market, they may provide security updates only for the software product that they have last placed on the market. They may do so only if the users of the relevant previous product versions have access to the latest product version free of charge and do not incur significant additional costs to adjust the hardware and software environment in which they operate the product.**

**6b This Regulation shall not prevent manufacturers from maintaining publicly available archives of previously made available software versions if they provide in a clear and easily accessible manner information on risks associated with using software that are not supported or updated anymore.**

7. Before placing a product with digital elements on the market, manufacturers shall draw up the technical documentation referred to in Article 23.

They shall carry out the chosen conformity assessment procedures referred to in Article 24 or have them carried out.

Where compliance of the product with digital elements with the essential requirements set out in Section 1 of Annex I and of the processes put in place by the manufacturer with the essential requirements set out in Section 2 of Annex I has been demonstrated by that conformity assessment procedure, manufacturers shall draw up the EU declaration of conformity in accordance with Article 20 and affix the CE marking in accordance with Article 22.

8. Manufacturers shall keep the technical documentation and the EU declaration of conformity, ~~where relevant,~~ at the disposal of the market surveillance authorities for ten years after the product with digital elements has been placed on the market.

9. Manufacturers shall ensure that procedures are in place for products with digital elements that are part of a series of production to remain in conformity **with the requirements of this Regulation**. The manufacturer shall adequately take into account changes in the development and production process or in the design or characteristics of the product with digital elements and changes in the harmonised standards, European cybersecurity certification schemes or the common specifications referred to in Article 189 by reference to which the conformity of the product with digital elements is declared or by application of which its conformity is verified.

**9a. Manufacturers shall ensure that their products with digital elements bear a type, batch or serial number or other element allowing their identification, or, where that is not possible, on its packaging or in a document accompanying the product with digital elements.**

**9aa. Manufacturers shall indicate the name, registered trade name or registered trade mark of the manufacturer, and the postal address, ~~and the email address or other digital contact as well as, where applicable, the website at which the manufacturer can be contacted, on the product with digital elements or, where that is not possible, on its packaging or in a document accompanying the product with digital elements. The contact details shall be in a language which can be easily understood by users and market surveillance authorities~~**

10. Manufacturers shall ensure that products with digital elements are accompanied by the information and instructions set out in Annex II, in an electronic or physical form. Such information and instructions shall be **provided** in a language which can be easily understood by users **and market surveillance authorities**. They shall be clear, understandable, intelligible and legible. They shall allow for a secure installation, operation and use of the products with digital elements.

- 10a. **Manufacturers shall ensure that the end date for the expected product lifetime as referred to in paragraph 6, including at least the month and year, until which the manufacturer will at least ensure the effective handling of vulnerabilities in accordance with the essential requirements set out in Section 2 of Annex I to this Regulation is clearly and understandably specified at the time of purchase, in an easily accessible manner and where applicable onf the product with digital elements, its packaging or by digital means.**
11. **Manufacturers shall either provide a copy of the EU declaration of conformity or a simplified EU declaration of conformity with the product with digital elements. Where a simplified EU declaration of conformity is provided, it shall contain or included in the instructions and information set out in Annex II the exact internet address at which the full EU declaration of conformity can be accessed.**
12. **From the placing on the market and for the period of time referred to in paragraph 6 expected product lifetime or for a period of five years after the placing on the market of a product with digital elements, whichever is shorter, manufacturers who know or have reason to believe that the product with digital elements or the processes put in place by the manufacturer are not in conformity with the essential requirements set out in Annex I shall immediately take the corrective measures necessary to bring that product with digital elements or the manufacturer's processes into conformity, to withdraw or to recall the product, as appropriate.**
13. **Manufacturers shall, further to a reasoned request from a market surveillance authority, provide that authority, in a language which can be easily understood by it, with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the product with digital elements and of the processes put in place by the manufacturer with the essential requirements set out in Annex I. They shall cooperate with that authority, at its request, on any measures taken to eliminate adequately reduce the cybersecurity risks posed by the product with digital elements, which they have placed on the market.**
14. **A manufacturer that ceases its operations and, as a result, is not able to comply with the obligations laid down in this Regulation shall inform, before the cease of operation takes effect, the relevant market surveillance authorities about this situation, as well as, by any means available and to the extent possible, the users of the concerned products with digital elements placed on the market.**
15. **The Commission may, by means of implementing acts, specify the format and elements of the software bill of materials set out in Section 2, point (1), of Annex I. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).**

## *Article 11*

### *Reporting obligations of manufacturers*

1. **The manufacturers shall, without undue delay, notify any actively exploited vulnerability contained in the product with digital elements that they become aware of to the CSIRTs designated as coordinators pursuant to Article 12(1) of**

~~Directive (EU) 2022/2555, in accordance with paragraph 2b of this Article. and in any event within 24 hours of becoming aware of it, notify to ENISA any actively exploited vulnerability contained in the product with digital elements. The notification shall include details concerning that vulnerability and, where applicable, any corrective or mitigating measures taken. ENISA shall, without undue delay, unless for justified cybersecurity risk related grounds, forward the notification to the CSIRT designated for the purposes of coordinated vulnerability disclosure in accordance with Article [Article X] of Directive [Directive XXX/XXXX (NIS2)] of Member States concerned upon receipt and inform the market surveillance authority about the notified vulnerability.~~

- 1a. For the purpose of the notification referred to in paragraph 1, the manufacturers shall submit:**
  - a) Without undue delay and in any event within 24 hours of becoming aware of the actively exploited vulnerability, an early warning which shall provide general information, as available, about the product with digital elements concerned, the nature of the exploit and of the respective vulnerability. The early warning shall also indicate, where applicable, the Member States on the territory of which the manufacturer is aware that their product with digital elements has been made available. Where applicable, the early warning shall also indicate any corrective or mitigating measures taken, corrective or mitigating measures that users can take, and include an indication of how sensitive the manufacturer deems the notified information to be.**
  - b) Without undue delay and in any event within 72 hours of becoming aware of the actively exploited vulnerability, a notification updating the information referred to in point (a). Where applicable, the notification shall indicate any available information about the actively exploited vulnerability, the status of remediation and any corrective or mitigating measures taken.**
- 2. The manufacturers shall, ~~without undue delay,~~ notify any incident having an impact on the security of the product with digital elements that they become aware of to the CSIRTs designated as coordinators pursuant to Article 12(1) of Directive (EU) 2022/2555, in accordance with paragraph 2b of this Article.**
- 2a. For the purpose of the notification referred to in paragraph 2, the manufacturers shall submit:**
  - a) Without undue delay and in any event within 24 hours of becoming aware of the incident, an early warning which shall provide general information, as available, about the nature of the incident and shall indicate whether the incident is suspected of being caused by unlawful or malicious acts or could have a cross-border impact. The early warning shall also indicate, where applicable, the Member States on the territory of which the manufacturer is aware that their product with digital elements has been made available. Where applicable, the early warning shall also indicate any corrective or mitigating measures taken, corrective or mitigating measures that users can take, and include an indication of how sensitive the manufacturer deems the notified information to be.**
  - b) Without undue delay and in any event within 72 hours of becoming aware of the incident, an incident notification which shall include information on the severity and impact of the incident, and, where applicable, update the**

information referred to in point (a). The notification shall also include, if available, information on the indicators of compromise.

- 2b. The notifications referred to in paragraphs 1 and 2 shall be submitted through one of the electronic notification end-points of the single reporting platform referred to in paragraph 2c.

Where the manufacturers have their main establishment in the Union, they shall submit the notifications referred to in paragraphs 1 and 2 through the electronic notification end-point of the CSIRT designated as coordinator pursuant to Article 12(1) of Directive (EU) 2022/2555 of the Member State in which they have their main establishment.

For the purposes of this Regulation, a manufacturer shall be considered to have its main establishment in the Union in the Member State where the decisions related to the cybersecurity of its products with digital elements are predominantly taken.

Where manufacturers have no main establishment in the Union, they shall notify via the single reporting platform to the CSIRT designated as coordinator pursuant to Article 12(1) of Directive (EU) 2022/2555 in the Member State of their choice, ~~or to all CSIRTs designated as coordinators pursuant to Article 12(1) of Directive (EU) 2022/2555.~~

- 2c. For the purposes of the notifications referred to in paragraphs 1 and 2, a single reporting platform shall be established, and the day-to-day operations managed and maintained by ENISA. The architecture of the single reporting platform shall allow Member States and ENISA to put in place their own electronic notification end-points.

~~The CSIRTs network established pursuant to Article 15 of Directive (EU) 2022/2555 shall be consulted for the organisational matters regarding the establishment, maintenance and secure operation of the single reporting platform, including the operational and security arrangements for the notification forms and for accessing information stored on the platform as well as the security arrangements for setting up the electronic notification end-points by the CSIRTs at national level.~~

The initial recipient of a notification shall, without delay, disseminate the notification via the single reporting platform to all the CSIRTs designated as coordinators pursuant to Article 12(1) of Directive (EU) 2022/2555 on whose territory it is aware that the product with digital elements has been made available and to ENISA. In exceptional circumstances and in particular upon request by the manufacturer, the dissemination of the notification may be delayed based on justified cybersecurity related grounds for a period of time that is strictly necessary, including in cases where a vulnerability is subject to a coordinated vulnerability disclosure procedure as referred to in Article 12(1) of Directive (EU) 2022/2555. The CSIRTs network shall adopt guidelines on the terms and conditions for applying the aforementioned cybersecurity related grounds.

~~The single reporting platform shall allow appropriate access of market surveillance authorities on whose territory a product with digital elements has been made available to information regarding an actively exploited vulnerability in that~~

product or an incident having an impact on the security of the product with digital elements.

After receiving a notification regarding an actively exploited vulnerability in a product with digital elements or regarding an incident having an impact on the security of a product with digital elements, the CSIRTs shall provide market surveillance authorities of their respective Member States with the information necessary for the market surveillance authorities to fulfil their obligations under this Regulation.

2d. The CSIRTs network established pursuant to Article 15 of Directive (EU) 2022/2555 shall provide guidance on the organisational matters regarding the establishment, maintenance and secure operation of the single reporting platform, including at least the following:

- a) operational aspects related to the establishment, operation and maintenance of the platform as well as the electronic notification end-points;
- b) security arrangements related to the establishment, operation and maintenance of the platform, as well as the electronic notification end-points setup by the CSIRTs at national level, including security aspects related to the access to information stored on the platform;
- c) the type of information and format of the notifications;
- d) data storage and data minimisation aspects with regard to the received notifications.

~~2aaa. In duly justified cases and in agreement with the CSIRTs referred to in paragraphs 1 and 2, manufacturers can may deviate from the deadlines laid down in paragraphs 2a and 2aa. In particular, a deviation from the deadlines provided for in paragraph 2a can be justified in cases where there is an ongoing process of developing a mitigation measure.~~

2aaaa. Manufacturers of products with digital elements shall have the possibility to voluntarily report vulnerabilities of which active exploitation has not yet been observed.

2aaaaa. Where a CSIRT designated as coordinator pursuant to Article 12(1) of Directive (EU) 2022/2555 has been made aware of an actively exploited vulnerability as part of a coordinated vulnerability disclosure procedure as referred to in Article 12(1) of Directive (EU) 2022/2555, the manufacturer of the relevant product with digital elements shall not be subject to the notification obligation referred to paragraph 1. This does not prevent manufacturers from notifying such a vulnerability on a voluntary basis in accordance with the procedure laid down in this Article.

2ab. Where a third party other than the manufacturer notifies an actively exploited vulnerability or an incident having an impact on the security of a product with digital elements under the scope of this Regulation to a CSIRT designated as coordinator pursuant to Article 12(1) of Directive (EU) 2022/2555, that CSIRT shall without undue delay inform the manufacturer.



3. ENISA **may** submit to the European cyber crisis liaison organisation network (EU-CyCLONe) established **under** Article **16** of Directive (EU) **2022/2555** information notified pursuant to paragraphs **1 (a), 1 (b), and 2a (xa) and 2a (b)** if such information is relevant for the coordinated management of large-scale cybersecurity incidents and crises at an operational level. **For the purpose of determining such relevance, ENISA may consider technical analyses performed by the CSIRTs network, where available.**
4. The manufacturer shall inform, ~~without undue delay and~~ after becoming aware, the users of the product with digital elements about **the an actively exploited vulnerability or an incident having an impact on the security of the product with digital elements** and, where necessary, about corrective measures that the user can deploy to mitigate the impact of that **vulnerability or** incident, **where appropriate in a structured and easily automatically processible machine-readable format.**
5. The Commission may, by means of implementing acts, specify further the type of information, format and procedure of the notifications submitted pursuant to paragraphs 1 ~~to 2~~**aba** of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).
6. ENISA, on the basis of the notifications received pursuant to paragraphs 1 and 2, shall prepare a biennial technical report on emerging trends regarding cybersecurity risks in products with digital elements and submit it to the Cooperation Group **established under** Article ~~{Article X}~~ **14** of Directive (EU) **2022/2555** ~~{Directive XXX/XXXX (NIS2)}~~. The first such report shall be submitted within 24 months after the obligations laid down in paragraphs 1 and 2 start applying.
7. Manufacturers shall, upon identifying a vulnerability in a component, including in an open source component, which is integrated in the product with digital elements, report the vulnerability to the person or entity maintaining the component. **Where manufacturers have developed a software modification to address the vulnerability in that component, they shall share the relevant code with the person or entity maintaining the component.**

## *Article 12*

### *Authorised representatives*

1. A manufacturer may appoint an authorised representative ~~by a written mandate~~.
2. The obligations laid down in Article 10(1) to (7) first indent and (9) shall not form part of the authorised representative's mandate.
3. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
  - (a) keep the EU declaration of conformity referred to in Article 20 and the technical documentation referred to in Article 23 at the disposal of the market surveillance authorities for ten years after the product with digital elements has been placed on the market;

- (b) further to a reasoned request from a market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the product with digital elements;
- (c) cooperate with the market surveillance authorities, at their request, on any action taken to eliminate the **cybersecurity** risks posed by a product with digital elements covered by the authorised representative's mandate.

### *Article 13*

#### *Obligations of importers*

1. Importers shall only place on the market products with digital elements that comply with the essential requirements set out in Section 1 of Annex I and where the processes put in place by the manufacturer are compliant with the essential requirements set out in Section 2 of Annex I.
2. Before placing a product with digital elements on the market, importers shall ensure that:
  - (a) the appropriate conformity assessment procedures referred to in Article 24 have been carried out by the manufacturer;
  - (b) the manufacturer has drawn up the technical documentation;
  - (c) the product with digital elements bears the CE marking referred to in Article 22 and is accompanied by **the required documents as referred to in Article 10(11) and the information and instructions for use as set out in Annex II in a language which can be easily understood by users and market surveillance authorities.**
  - (d) **The manufacturer has complied with the requirements set out in Article 10(9a), 10(9aa) and 10(10a).**
3. Where an importer considers or has reason to believe that a product with digital elements or the processes put in place by the manufacturer are not in conformity with the essential requirements set out in Annex I, the importer shall not place the product on the market until that product or the processes put in place by the manufacturer have been brought into conformity with the essential requirements set out in Annex I. Furthermore, where the product with digital elements presents a significant cybersecurity risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.
4. Importers shall indicate their name, registered trade name or registered trademark, the postal address ~~and website~~, the email address **or other digital contact as well as, where applicable, the website** at which they can be contacted on the product with digital elements or, where that is not possible, on its packaging or in a document accompanying the product with digital elements. The contact details shall be in a language easily understood by users and market surveillance authorities.
5. ~~Importers shall ensure that the product with digital elements is accompanied by the instructions and information set out in Annex II in a language which can be easily understood by users.~~

6. Importers who know or have reason to believe that a product with digital elements, which they have placed on the market, or the processes put in place by its manufacturer, are not in conformity with the essential requirements set out in Annex I shall immediately take the corrective measures necessary to bring that product with digital elements or the processes put in place by its manufacturer into conformity with the essential requirements set out in Annex I, or to withdraw or recall the product, if appropriate.

Upon identifying a vulnerability in the product with digital elements, importers shall inform the manufacturer without undue delay about that vulnerability. Furthermore, where the product with digital elements presents a significant cybersecurity risk, importers shall immediately inform the market surveillance authorities of the Member States in which they made the product with digital elements available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

7. Importers shall, for ten years after the product with digital elements has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.
8. Importers shall, further to a reasoned request from a market surveillance authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the product with digital elements with the essential requirements set out in Section 1 of Annex I as well as of the processes put in place by the manufacturer with the essential requirements set out in Section 2 of Annex I in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any ~~measures~~ **action** taken to ~~eliminate~~ **adequately reduce** the cybersecurity risks posed by a product with digital elements, which they have placed on the market.
9. When the importer of a product with digital elements becomes aware that the manufacturer of that product ceased its operations and, as result, is not able to comply with the obligations laid down in this Regulation, the importer shall inform the relevant market surveillance authorities about this situation, as well as, by any means available and to the extent possible, the users of the products with digital elements placed on the market.

#### *Article 14*

##### *Obligations of distributors*

1. When making a product with digital elements available on the market, distributors shall act with due care in relation to the requirements of this Regulation.
2. Before making a product with digital elements available on the market, distributors shall verify that:
  - (a) the product with digital elements bears the CE marking;
  - (b) the manufacturer and the importer have complied with the obligations set out respectively in Articles 10(9a), 10(9aa), 10(10), 10(10a), 10(11) and 13(4).

3. Where a distributor considers or has reason to believe that a product with digital elements or the processes put in place by the manufacturer are not in conformity with the essential requirements set out in Annex I, the distributor shall not make the product with digital elements available on the market until that product or the processes put in place by the manufacturer have been brought into conformity. Furthermore, where the product with digital elements poses a significant cybersecurity risk, the distributor shall inform **without undue delay** the manufacturer and the market surveillance authorities to that effect.
4. Distributors who know or have reason to believe that a product with digital elements, which they have made available on the market, or the processes put in place by its manufacturer are not in conformity with the essential requirements set out in Annex I shall make sure that the corrective measures necessary to bring that product with digital elements or the processes put in place by its manufacturer into conformity are taken, or to withdraw or recall the product, if appropriate.

Upon identifying a vulnerability in the product with digital elements, distributors shall inform the manufacturer without undue delay about that vulnerability. Furthermore, where the product with digital elements presents a significant cybersecurity risk, distributors shall immediately inform the market surveillance authorities of the Member States in which they have made the product with digital elements available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.
5. Distributors shall, further to a reasoned request from a market surveillance authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the product with digital elements and the processes put in place by its manufacturer with the essential requirements set out in Annex I in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the cybersecurity risks posed by a product with digital elements, which they have made available on the market.
6. When the distributor of a product with digital elements becomes aware that the manufacturer of that product ceased its operations and, as result, is not able to comply with the obligations laid down in this Regulation, the distributor shall inform, **without undue delay**, the relevant market surveillance authorities about this situation, as well as, by any means available and to the extent possible, the users of the products with digital elements placed on the market.

#### *Article 15*

##### *Cases in which obligations of manufacturers apply to importers and distributors*

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Articles 10 and 11(1), (2), (4) and (7) where that importer or distributor places a product with digital elements on the market under his or her name or trademark or carries out a substantial modification of the product with digital elements already placed on the market.

#### *Article 16*

##### *Other cases in which obligations of manufacturers apply*

A natural or legal person, other than the manufacturer, the importer or the distributor, that carries out a substantial modification of the product with digital elements shall be considered a manufacturer for the purposes of this Regulation.

That person shall be subject to the obligations of the manufacturer set out in Articles 10 and 11(1), (2), (4) and (7), for the part of the product that is affected by the substantial modification or, if the substantial modification has an impact on the cybersecurity of the product with digital elements as a whole, for the entire product.

## *Article 17*

### *Identification of economic operators*

1. Economic operators shall, on request and where the information is available, provide to the market surveillance authorities the following information:
  - (a) name and address of any economic operator who has supplied them with a product with digital elements;
  - (b) name and address of any economic operator to whom they have supplied a product with digital elements;
2. Economic operators shall be able to present the information referred to in paragraph 1 for ten years after they have been supplied with the product with digital elements and for ten years after they have supplied the product with digital elements.

## *Article 18*

### *Presumption of conformity*

1. Products with digital elements and processes put in place by the manufacturer which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential requirements **set out in Annex I** covered by those standards or parts thereof.
- ~~2. Products with digital elements and processes put in place by the manufacturer, which are in conformity with the common specifications referred to in Article 19 shall be presumed to be in conformity with the essential requirements set out in Annex I, to the extent those common specifications cover those requirements.~~
2. **The Commission shall, as provided in Article 10(1) of Regulation (EU) No 1025/2012, request one or more European standardisation organisations to draft harmonised standards for the essential requirements set out in Annex I.**

- 3. The Commission may adopt implementing acts establishing common specifications covering technical requirements that provide a means to comply with the essential requirements set out in Annex I for products with digital elements within the scope of this Regulation.**

**Those implementing acts shall only be adopted where the following conditions are fulfilled:**

- (a) the Commission has requested, pursuant to Article 10(1) of Regulation (EU) No 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential requirements set out in Annex I and:**
  - (i) the request has not been accepted; or**
  - (ii) the harmonised standards addressing that request are not delivered within the deadline set in accordance with Article 10(1) of Regulation (EU) No 1025/2012; or**
  - (iii) the harmonised standards do not comply with the request; and**
- (b) no reference to harmonised standards covering the relevant essential requirements set out in Annex I has been published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.**

**Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).**

- 4. Before preparing the draft implementing act referred to in paragraph 3, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 3 have been fulfilled.**

5. When preparing the draft implementing act referred to in paragraph 3, the Commission shall take into account the views of relevant bodies or the expert group and shall duly consult all relevant stakeholders.
6. Products with digital elements and processes put in place by the manufacturer which are in conformity with the common specifications ~~referred to in Article 19~~ **established by implementing acts referred to in paragraph 3, or parts thereof**, shall be presumed to be in conformity with the essential requirements set out in Annex I, ~~to the extent covered by those common specifications or parts thereof~~ ~~cover those requirements~~.
7. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess the harmonised standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal the implementing acts referred to in paragraph 3, or parts thereof which cover the same essential requirements as those covered by that harmonised standard.
8. When a Member State considers that a common specification does not entirely satisfy the essential requirements set out in Annex I, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and may, if appropriate, amend the implementing act establishing the common specification in question.
39. Products with digital elements and processes put in place by the manufacturer for which an EU statement of conformity or certificate<sup>22</sup> has been issued under a European cybersecurity certification scheme adopted as per Regulation (EU) 2019/881 ~~and specified as per paragraph 4-10~~, shall be presumed to be in conformity with the essential requirements set out in Annex I **and related conformity assessment procedures** ~~in so far as the EU statement of conformity or cybersecurity certificate, or parts thereof, cover those requirements~~. **For the purposes of the presumption of conformity, products with digital elements that need to undergo the conformity assessment procedures referred to in Article 24 (2) and (3) shall have a European cybersecurity certificate that refers to assurance level “substantial” or “high”.**
- 4-10. The Commission ~~is empowered~~ **may**, by means of implementing acts, ~~to~~ specify the European cybersecurity certification schemes adopted pursuant to Regulation (EU) 2019/881 that can be used to demonstrate conformity with the essential requirements or parts thereof as set out in Annex I **and related conformity assessment procedures**. ~~Furthermore, where applicable, the Commission shall specify if for which assurance levels, a cybersecurity certificate issued under such schemes eliminates the obligation of a manufacturer to carry out a third-party conformity assessment for the corresponding requirements, as set out in Article 24(2)(a), (b), (3)(a) and (b).~~ Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).

*Article 19*

*{Common specifications}*



~~Where harmonised standards referred to in Article 18 do not exist or where the Commission considers that the relevant harmonised standards are insufficient to satisfy the requirements of this Regulation or to comply with the standardisation request of the Commission, or where there are undue delays in the standardisation procedure or where the request for harmonised standards by the Commission has not been accepted by the European standardisation organisations, the Commission is empowered, by means of implementing acts, to adopt common specifications in respect of the essential requirements set out in Annex I. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).~~

## *Article 20*

### *EU declaration of conformity*

1. The EU declaration of conformity shall be drawn up by manufacturers in accordance with Article 10(7) and state that the fulfilment of the applicable essential requirements set out in Annex I has been demonstrated.
2. The EU declaration of conformity shall have the model structure set out in Annex IV and shall contain the elements specified in the relevant conformity assessment procedures set out in Annex VI. Such a declaration shall be continuously updated. It shall be made available in the language or languages required by the Member State in which the product with digital elements is placed on the market or made available **on the market**.  
**The simplified EU declaration of conformity referred to in Article 10(11) shall contain the model structure set out in Annex [XX] and shall be continuously updated. It shall be made available in the languages required by the Member State in which the product with digital elements is placed on the market or made available on the market. The full text of the EU declaration of conformity shall be available at the internet address referred to in the simplified EU declaration of conformity, in the languages required by the Member State in which the product with digital elements is placed on the market or made available on the market.**
3. Where a product with digital elements is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.
4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product.
5. The Commission is empowered to adopt delegated acts in accordance with Article 50 to supplement this Regulation by adding elements to the minimum content of the EU declaration of conformity set out in Annex IV to take account of technological developments.

## *Article 21*

### *General principles of the CE marking*

The CE marking as defined in Article 3(32) shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

## Article 22

### *Rules and conditions for affixing the CE marking*

1. The CE marking shall be affixed visibly, legibly and indelibly to the product with digital elements. Where that is not possible or not warranted on account of the nature of the product with digital elements, it shall be affixed to ~~the packaging and~~ **the accompanying documents and where applicable to the packaging** ~~EU declaration of conformity referred to in Article 20 accompanying the product with digital elements. For products with digital elements which are in the form of software, the CE marking shall be affixed either to the EU declaration of conformity referred to in Article 20 or on the website accompanying the software product.~~
2. On account of the nature of the product with digital elements, the height of the CE marking affixed to the product with digital elements may be lower than 5 mm, provided that it remains visible and legible.
3. The CE marking shall be affixed before the product with digital elements is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use set out in implementing acts referred to in paragraph 6.
4. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the conformity assessment procedure based on full quality assurance (based on module H) referred to in Article 24.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or the manufacturer's authorised representative.

5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking. Where the product with digital elements is subject to other Union legislation which also provides for the affixing of the CE marking, the CE marking shall indicate that the product also fulfils the requirements of that other legislation.
6. The Commission may, by means of implementing acts, lay down technical specifications for pictograms or any other marks related to the security of the products with digital elements, and mechanisms to promote their use. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).

## Article 23

### *Technical documentation*

1. The technical documentation shall contain all relevant data or details of the means used by the manufacturer to ensure that the product with digital elements and the processes put in place by the manufacturer comply with the essential requirements set out in Annex I. It shall at least contain the elements set out in Annex V, **or, in the case of small and micro enterprises, any equivalent documentation meeting the same objectives, unless deemed inappropriate by the market surveillance authority.**

2. The technical documentation shall be drawn up before the product with digital elements is placed on the market and shall be continuously updated, ~~where appropriate, during the expected product lifetime or during a period of five years after the placing on the market of a product with digital elements, whichever is shorter.~~
3. For products with digital elements referred to in Articles 8 and 24(4) that are also subject to other Union acts, one single technical documentation shall be drawn up containing the information referred to in Annex V of this Regulation and the information required by those respective Union acts.
4. The technical documentation and correspondence relating to any conformity assessment procedure shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.
5. The Commission is empowered to adopt delegated acts in accordance with Article 50 to supplement this Regulation by the elements to be included in the technical documentation set out in Annex V to take account of technological developments, as well as developments encountered in the implementation process of this Regulation.

#### *Article 24*

##### *Conformity assessment procedures for products with digital elements*

1. The manufacturer shall perform a conformity assessment of the product with digital elements and the processes put in place by the manufacturer to determine whether the essential requirements set out in Annex I are met. The manufacturer ~~or the manufacturer's authorised representative~~ shall demonstrate conformity with the essential requirements by using ~~one~~ **any** of the following procedures:
  - (a) the internal control procedure (based on module A) set out in Annex VI; ~~or~~
  - (b) the EU-type examination procedure (based on module B) set out in Annex VI followed by conformity to EU-type based on internal production control (based on module C) set out in Annex VI; ~~or~~
  - (c) conformity assessment based on full quality assurance (based on module H) set out in Annex VI; ~~or~~
  - (d) **where available and applicable, a European cybersecurity certification scheme as specified in Article 18(39) and (410) at any assurance level.**
2. Where, in assessing the compliance of the ~~critical~~ product with digital elements of class I as set out in Annex III and the processes put in place by its manufacturer with the essential requirements set out in Annex I, the manufacturer ~~or the manufacturer's authorised representative~~ has not applied or has applied only in part harmonised standards, common specifications or European cybersecurity certification schemes as referred to in Article 18, or where such harmonised standards, common specifications or European cybersecurity certification schemes do not exist, the product with digital elements concerned and the processes put in place by the manufacturer shall be submitted with regard to those essential requirements to ~~either~~ **any** of the following procedures:

- (a) ~~the~~ EU-type examination procedure (based on module B) ~~provided for~~ **set out** in Annex VI followed by conformity to EU-type based on internal production control (based on module C) set out in Annex VI; ~~or~~
  - (b) conformity assessment based on full quality assurance (based on module H) set out in Annex VI-; **or**
  - (c) **where available and applicable, a European cybersecurity certification scheme as specified in Article 18(9) and (10) at assurance level ‘substantial’ or ‘high’.**
3. Where the product is a ~~critical~~ product with digital elements of class II as set out in Annex III, the manufacturer ~~or the manufacturer’s authorised representative~~ shall demonstrate conformity with the essential requirements set out in Annex I by using ~~one~~ **any** of the following procedures:
- (a) EU-type examination procedure (based on module B) set out in Annex VI followed by conformity to EU-type based on internal production control (based on module C) set out in Annex VI; ~~or~~
  - (b) conformity assessment based on full quality assurance (based on module H) set out in Annex VI-; **or**
  - (c) **where available and applicable, a European cybersecurity certification scheme as specified in Article 18 (9) and (10) at assurance level ‘substantial’ or ‘high’.**
- 3aa. Highly critical products listed in Annex IIIa shall demonstrate conformity with the essential requirements set out in Annex I by using one of the following procedures:**
- (a) **a European cybersecurity certification scheme in accordance with Article 6a (1) , or,**
  - (b) **where the conditions in Article 6a (1) are not met, any of the procedures referred to in paragraph 3 of this Article.**
4. Manufacturers of products with digital elements that are classified as EHR systems under the scope of Regulation [the European Health Data Space Regulation] shall demonstrate conformity with the essential requirements laid down in Annex I of this Regulation using the relevant conformity assessment procedure as required by Regulation [Chapter III of the European Health Data Space Regulation].
5. ~~Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises (SMEs) when setting the fees for conformity assessment procedures and reduce those fees proportionately to their specific interests and needs.~~ **The specific interests and needs of SMEs<sup>35</sup>, including start-ups, shall be taken into account when setting the fees for conformity assessment.**

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<sup>35</sup> **A definition has been added.**

*Article 24a*

*Support measures for small and micro enterprises*

1. Member States ~~shall~~ may undertake the following actions, tailored to the needs of small and micro enterprises:
  - (a) organise specific awareness raising and training activities about the application of this Regulation;
  - (b) where appropriate, establish a dedicated channel for communication with small and micro enterprises and, as appropriate, local public authorities to provide advice and respond to queries about the implementation of this Regulation.
  - (c) where appropriate, support testing and conformity assessment activities.
2. The Commission shall ensure the development of guidance and standardised templates for small and micro enterprises for the matters covered by in relation to the implementation of this Regulation.
3. Small and micro enterprises may provide the elements of the technical documentation specified in Annex V in a simplified manner. For this purpose, the Commission, in consultation with the market surveillance authorities, shall establish a simplified technical documentation form targeted at the needs of small and micro enterprises. Where a small or micro enterprise opts to provide the information required in Annex V in a simplified manner, it shall use the form referred to in this paragraph. Notified bodies shall accept the form for the purpose of conformity assessment.

## CHAPTER IV

### NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

#### *Article 25*

##### *Notification*

Member States shall notify the Commission and the other Member States of ~~conformity assessment~~ bodies authorised to carry out conformity assessments in accordance with this Regulation.

#### *Article 26*

##### *Notifying authorities*

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 31.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
3. **Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in [Article 27] of this Regulation. In addition it shall have arrangements to cover liabilities arising out of its activities.**
4. **The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.**

#### *Article 27*

##### *Requirements relating to notifying authorities*

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
2. A notifying authority shall be organised and shall function so as to safeguard the objectivity and impartiality of its activities.
3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on commercial or competitive basis.
5. A notifying authority shall safeguard the confidentiality of the information it obtains.
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

#### *Article 28*

##### *Information obligation on notifying authorities*

1. Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.
2. The Commission shall make that information publicly available.

#### *Article 29*

##### *Requirements relating to notified bodies*

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 12.
2. A conformity assessment body shall be established under national law and have legal personality.
3. A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, development, production, provision, assembly, use or maintenance of products with digital elements which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, developer, manufacturer, supplier, **importer, distributor**, installer, purchaser, owner, user or maintainer of the products with digital elements which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.



A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, development, production, **import, distribution**, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.
6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks referred to in Annex VI and in relation to which it has been notified, regardless of whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of products with digital elements in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) ~~staff~~ **personnel** with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment activities shall have the following:
  - (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
  - (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
  - (c) appropriate knowledge and understanding of the essential requirements **set out in Annex I**, of the applicable harmonised standards **as well as the common specifications** and of the relevant provisions of Union harmonisation legislation and of its implementing acts;
  - (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
8. The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.

The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.
9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex VI or any provision of national law giving effect to it, except in relation to the market surveillance authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected. The conformity assessment body shall have documented procedures ensuring compliance with this paragraph.
11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 40 and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.
12. Conformity assessment bodies shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, in particular taking into account the interests of SMEs in relation to fees.

### *Article 30*

#### *Presumption of conformity of notified bodies*

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the

*Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 29 in so far as the applicable harmonised standards cover those requirements.

### *Article 31*

#### *Subsidiaries of and subcontracting by notified bodies*

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 29 and shall inform the notifying authority accordingly.
2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the manufacturer.
4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.

### *Article 32*

#### *Application for notification*

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.
2. That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment procedure or procedures and the product or products for which that body claims to be competent, as well as by an accreditation certificate, where ~~applicable one exists~~, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 29.
3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 29.

### *Article 33*

#### *Notification procedure*

1. Notifying authorities may notify only conformity assessment bodies, which have satisfied the requirements laid down in Article 29.
2. The notifying authority shall notify the Commission and the other Member States using the New Approach Notified and Designated Organisations (NANDO) information system developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and product or products concerned and the relevant attestation of competence.
4. Where a notification is not based on an accreditation certificate as referred to in Article 32(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 29.
5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Regulation.

6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

#### *Article 34*

##### *Identification numbers and lists of notified bodies*

1. The Commission shall assign an identification number to a notified body.  
  
It shall assign a single such number even where the body is notified under several Union acts.
2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been allocated to them and the activities for which they have been notified.

The Commission shall ensure that that list is kept up to date.

#### *Article 35*

##### *Changes to notifications*

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 29, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

## Article 36

### *Challenge of the competence of notified bodies*

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.
2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.
3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

## Article 37

### *Operational obligations of notified bodies*

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Article 24 and Annex VI.
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.
3. Notified bodies shall however respect the degree of rigour and the level of protection required for the compliance of the product with the provisions of Regulation.
4. Where a notified body finds that requirements laid down in Annex I or in corresponding harmonised standards or in common specifications as referred to in Article 198 have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a ~~conformity~~ certificate **of conformity**.
5. Where, in the course of the monitoring of conformity following the issuance of a certificate, a notified body finds that a product no longer complies with the requirements laid down in this Regulation, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.
6. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

### *Article 37a*

#### *Appeal against decisions of notified bodies*

**Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.**

### *Article 38*

#### *Information obligation on notified bodies*

1. Notified bodies shall inform the notifying authority of the following:
  - (a) any refusal, restriction, suspension or withdrawal of a certificate;
  - (b) any circumstances affecting the scope of and conditions for notification;
  - (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
  - (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.
2. Notified bodies shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

### *Article 39*

#### *Exchange of experience*

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

### *Article 40*

#### *Coordination of notified bodies*

1. The Commission shall ensure that appropriate coordination and cooperation between notified bodies are put in place and properly operated in the form of a cross-sectoral group of notified bodies.
2. Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

## CHAPTER V

### MARKET SURVEILLANCE AND ENFORCEMENT

#### *Article 41*

##### *Market surveillance and control of products with digital elements in the Union market*

1. Regulation (EU) 2019/1020 shall apply to the products with digital elements within the scope of this Regulation.
2. Each Member State shall designate one or more market surveillance authorities for the purpose of ensuring the effective implementation of this Regulation. Member States may designate an existing or new authority to act as market surveillance authority for this Regulation.
3. Where relevant, the market surveillance authorities shall cooperate with the national cybersecurity certification authorities designated under Article 58 of Regulation (EU) 2019/881 and exchange information on a regular basis. With respect to the supervision of the implementation of the reporting obligations pursuant to Article 11 of this Regulation, the designated market surveillance authorities shall cooperate with ENISA.
4. Where relevant, the market surveillance authorities shall cooperate with other market surveillance authorities designated on the basis of other Union harmonisation legislation for other products, and exchange information on a regular basis.
5. Market surveillance authorities shall cooperate, as appropriate, with the authorities supervising Union data protection law. Such cooperation includes informing these authorities of any finding relevant for the fulfilment of their competences, including when issuing guidance and advice pursuant to paragraph 8 of this Article if such guidance and advice concerns the processing of personal data.

Authorities supervising Union data protection law shall have the power to request and access any documentation created or maintained under this Regulation when access to that documentation is necessary for the fulfilment of their tasks. They shall inform the designated market surveillance authorities of the Member State concerned of any such request.

6. Member States shall ensure that the designated market surveillance authorities are provided with adequate financial, ~~and~~ human **and technical** resources, **including, where appropriate, processing automation tools**, to fulfil their tasks under this Regulation.
7. The Commission shall facilitate the exchange of experience between designated market surveillance authorities.
8. Market surveillance authorities may provide guidance and advice to economic operators on the implementation of this Regulation, with the support of the Commission.

9. The market surveillance authorities shall report to the Commission on an annual basis the outcomes of relevant market surveillance activities. The designated market surveillance authorities shall report, without delay, to the Commission and relevant national competition authorities any information identified in the course of market surveillance activities that may be of potential interest for the application of Union competition law.
  10. For products with digital elements in the scope of this Regulation classified as high-risk AI systems according to Article [Article 6] of the Regulation [the AI Regulation], the market surveillance authorities designated for the purposes of the Regulation [the AI Regulation] shall be the authorities responsible for market surveillance activities required under this Regulation. The market surveillance authorities designated pursuant to Regulation [the AI Regulation] shall cooperate, as appropriate, with the market surveillance authorities designated pursuant to this Regulation and, with respect to the supervision of the implementation of the reporting obligations pursuant to Article 11, with ENISA. Market surveillance authorities designated pursuant to Regulation [the AI Regulation] shall in particular inform market surveillance authorities designated pursuant to this Regulation of any finding relevant for the fulfilment of their tasks in relation to the implementation of this Regulation.
  11. A dedicated administrative cooperation group (ADCO) shall be established for the uniform application of this Regulation, pursuant to Article 30(2) of Regulation (EU) 2019/1020. This ADCO shall be composed of representatives of the designated market surveillance authorities and, if appropriate, representatives of single liaison offices.
- 11.a ADCO may publish statistics about the average expected product lifetime, as specified by the manufacturer pursuant to article 10 (10a), per category of products with digital elements.**

#### *Article 42*

##### *Access to data and documentation*

Where necessary to assess the conformity of products with digital elements and the processes put in place by their manufacturers with the essential requirements set out in Annex I and upon a reasoned request, the market surveillance authorities shall be granted access to the data, **in a language easily understood by them**, required to assess the design, development, production and vulnerability handling of such products, including related internal documentation of the respective economic operator.

#### *Article 43*

##### *Procedure at national level concerning products with digital elements presenting a significant cybersecurity risk*

1. Where the market surveillance authority of a Member State has sufficient reasons to consider that a product with digital elements, including its vulnerability handling, presents a significant cybersecurity risk, it shall carry out an evaluation of the product with digital elements concerned in respect of its compliance with ~~all~~ the requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authority.



Where, in the course of that evaluation, the market surveillance authority finds that the product with digital elements does not comply with the requirements laid down in this Regulation, it shall without delay require the relevant **economic** operator to take ~~all~~ appropriate corrective actions to bring the product **with digital elements** into compliance with those requirements, to withdraw it from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as ~~the market surveillance authority~~ may prescribe.

The market surveillance authority shall inform the relevant notified body accordingly. Article 18 of Regulation (EU) 2019/1020 shall apply to the ~~appropriate~~ corrective actions.

2. Where the market surveillance authority considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which it has required the **economic** operator to take.
3. The ~~manufacturer~~ **economic operator** shall ensure that ~~all~~ **any** appropriate corrective action is taken in respect of all the products with digital elements concerned that it has made available on the market throughout the Union.
4. Where the ~~manufacturer~~ **economic operator** of a product with digital elements does not take adequate corrective action within the period referred to in paragraph 1, second subparagraph, the market surveillance authority shall take ~~all~~ appropriate provisional measures to prohibit or restrict that product **with digital elements** from being made available on its national market, to withdraw it from that market or to recall it.

That authority shall ~~inform~~ **notify** the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant products with digital elements, the origin of ~~the~~ **that** product with digital elements, the nature of the alleged non-compliance and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant **economic** operator. In particular, the market surveillance authority shall indicate whether the non-compliance is due to one or more of the following:
  - (a) a failure of the product **with digital elements** or of the processes put in place by the manufacturer to meet the essential requirements set out in Annex I;
  - (b) shortcomings in the harmonised standards, cybersecurity certification schemes, or common specifications, referred to in Article 18.
6. The market surveillance authorities of the Member States other than the market surveillance authority of the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product **with digital elements** concerned, and, in the event of disagreement with the notified national measure, of their objections.
7. Where, within three months of receipt of the ~~information~~ **notification** referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed

justified. This is without prejudice to the procedural rights of the **economic** operator concerned in accordance with Article 18 of Regulation (EU) 2019/1020.

8. The market surveillance authorities of all Member States shall ensure that appropriate restrictive measures are taken in respect of the product **with digital elements** concerned, such as withdrawal of ~~that~~ product from their market, without delay.

#### *Article 44*

##### *Union safeguard procedure*

1. Where, within three months of receipt of the notification referred to in Article 43(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union ~~legislation~~**law**, the Commission shall without delay enter into consultation with the relevant Member State and the economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not within nine months from the notification referred to in Article 43(4) and notify ~~such~~**that** decision to the Member State concerned.
2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant product with digital elements is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.
3. Where the national measure is considered justified and the non-compliance of the product with digital elements is attributed to shortcomings in the harmonised standards, the Commission shall apply the procedure provided for in Article ~~40-11~~ of Regulation (EU) No 1025/2012.
4. Where the national measure is considered justified and the non-compliance of the product with digital elements is attributed to shortcomings in a European cybersecurity certification scheme as referred to in Article 18, the Commission shall consider whether to amend or repeal the implementing act as referred to in Article 18(4) that specifies the presumption of conformity concerning that certification scheme.
5. Where the national measure is considered justified and the non-compliance of the product with digital elements is attributed to shortcomings in common specifications as referred to in Article ~~198~~, the Commission shall consider whether to amend or repeal the implementing act referred to in Article ~~198~~ setting out those common specifications.

#### *Article 45*

##### *Procedure at EU level concerning products with digital elements presenting a significant cybersecurity risk*

1. Where the Commission has sufficient reasons to consider, including based on information provided by ENISA, that a product with digital elements that presents a significant cybersecurity risk is non-compliant with the requirements laid down in this Regulation, it ~~shall may request~~ **inform** the relevant market surveillance authorities. ~~to carry out an evaluation of compliance and follow the procedures referred to in Article 43. Where the market surveillance authorities carry out an evaluation of that product with digital~~

**elements that may present a significant cybersecurity risk in respect of its compliance with the requirements laid down in this Regulation, the procedures referred to in Articles 43 and 44 shall apply.**

2. In exceptional circumstances which justify an immediate intervention to preserve the good functioning of the internal market and where the Commission has sufficient reasons to consider that the product **with digital elements** referred to in paragraph 1 remains non-compliant with the requirements laid down in this Regulation and no effective measures have been taken by the relevant market surveillance authorities, the Commission may request ENISA to **provide an analysis to support** ~~carry out~~ an evaluation of compliance. The Commission shall inform the relevant market surveillance authorities accordingly. The relevant economic operators shall cooperate as necessary with ENISA.
3. Based on ~~ENISA's~~ **the evaluation referred to in paragraph 2**, the Commission may decide that a corrective or restrictive measure is necessary at Union level. To this end, it shall without delay consult the Member States concerned and the relevant economic operator or operators.
4. On the basis of the consultation referred to in paragraph 3, the Commission may adopt implementing acts to decide on corrective or restrictive measures at Union level, including ordering withdrawal **of the product with digital elements** from the market, or recalling **of it**, within a reasonable period, commensurate with the nature of the risk. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).
5. The Commission shall immediately communicate the ~~decision~~ **implementing acts** referred to in paragraph 4 to the relevant economic operator or operators. Member States shall implement those acts ~~referred to in paragraph 4~~ without delay and shall inform the Commission accordingly.
6. Paragraphs 2 to 5 are applicable for the duration of the exceptional situation that justified the Commission's intervention and for as long as the ~~respective~~ product **with digital elements concerned** is not brought in compliance with this Regulation.

#### *Article 46*

##### *Compliant products with digital elements which present a significant cybersecurity risk*

1. **The market surveillance authority of a Member State shall require an economic operator to take appropriate measures where, having performed an evaluation under Article 43, it finds that although a product with digital elements and the processes put in place by the manufacturer are in compliance with this Regulation, it presents a significant cybersecurity risk as well as a risk to:**
  - (a) **the health or safety of persons;**
  - (b) **the compliance with obligations under Union or national law intended to protect fundamental rights;**
  - (c) **the availability, authenticity, integrity or confidentiality of services offered using an electronic information system by entities of a type referred to in Annex I to Directive (EU) 2022/2555; or**

**(d) other aspects of public interest protection.**

**The measures referred to in the first subparagraph may include measures to ensure that the product with digital elements concerned and the processes put in place by the manufacturer no longer present the relevant risks [when made available on the market], withdrawal from the market of the product with digital elements concerned, or recalling of it, and shall be commensurate with the nature of those risks.**

- ~~1. Where, having performed an evaluation under Article 43, the market surveillance authority of a Member State finds that although a product with digital elements and the processes put in place by the manufacturer are in compliance with this Regulation, they present a significant cybersecurity risk and, in addition, they pose a risk to the health or safety of persons, to the compliance with obligations under Union or national law intended to protect fundamental rights, the availability authenticity, integrity or confidentiality of services offered using an electronic information system by essential entities of the type referred to in [Annex I to Directive XXX / XXXX (NIS2)] or to other aspects of public interest protection, it shall require the relevant operator to take all appropriate measures to ensure that the product with digital elements and the processes put in place by the manufacturer concerned, when placed on the market, no longer present that risk, to withdraw the product with digital elements from the market or to recall it within a reasonable period, commensurate with the nature of the risk.~~
2. The manufacturer or other relevant **economic** operators shall ensure that corrective action is taken in respect of the products with digital elements concerned that they have made available on the market throughout the Union within the timeline established by the market surveillance authority of the Member State referred to in paragraph 1.
3. The Member State shall immediately inform the Commission and the other Member States about the measures taken pursuant to paragraph 1. That information shall include all available details, in particular the data necessary for the identification of the products with digital elements concerned, the origin and the supply chain of those products with digital elements, the nature of the risks involved and the nature and duration of the national measures taken.
4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.
- ~~5. The Commission shall address its decision to the Member States.~~
6. Where the Commission has sufficient reasons to consider, including based on information provided by ENISA, that a product with digital elements, although compliant with this Regulation, presents the risks referred to in paragraph 1, it ~~may request~~ **shall inform** the relevant market surveillance authority. ~~or authorities to carry out an evaluation of compliance the risks and follow the procedures referred to in Article 43 and paragraphs 1, 2 and 3 of this Article.~~

7. In exceptional circumstances which justify an immediate intervention to preserve the good functioning of the internal market and where the Commission has sufficient reasons to consider that the product **with digital elements** referred to in paragraph 6 continues to present the risks referred to in paragraph 1, and no effective measures have been taken by the relevant national market surveillance authorities, the Commission may request ENISA to **provide an analysis to support**~~carry out~~ an evaluation of the risks presented by that product **with digital elements** and shall inform the relevant market surveillance authorities accordingly. The relevant economic operators shall cooperate as necessary with ENISA.
8. Based on ~~ENISA's~~ **the** evaluation referred to in paragraph 7, the Commission may establish that a corrective or restrictive measure is necessary at Union level. To this end, it shall without delay consult the Member States concerned and the relevant **economic** operator or operators.
9. On the basis of the consultation referred to in paragraph 8, the Commission may adopt implementing acts to decide on corrective or restrictive measures at Union level, including ordering withdrawal **of the product with digital elements** from the market, or recalling **of it**, within a reasonable period, commensurate with the nature of the risk. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).
10. The Commission shall immediately communicate the ~~decision~~ **implementing acts** referred to in ~~the~~ paragraph 9 to the relevant **economic** operator or operators. Member States shall implement ~~such~~ **those** acts without delay and shall inform the Commission accordingly.
11. Paragraphs 6 to 10 shall apply for the duration of the exceptional situation that justified the Commission's intervention and for as long as the ~~respective~~ product **with digital elements concerned** continues to present the risks referred to in paragraph 1.

#### *Article 47*

##### *Formal non-compliance*

1. Where the market surveillance authority of a Member State makes one of the following findings, it shall require the relevant manufacturer to end to the non-compliance concerned:
  - (a) the ~~conformity~~ **CE** marking has been affixed in violation of Articles 21 and 22;
  - (b) the ~~conformity~~ **CE** marking has not been affixed;
  - (c) the EU declaration of conformity has not been drawn up;
  - (d) the EU declaration of conformity has not been drawn up correctly;
  - (e) the identification number of the notified body, which is involved in the conformity assessment procedure, where applicable, has not been affixed;
  - (f) the technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product with digital elements from being made available on the market or ensure that it is recalled or withdrawn from the market.

#### *Article 48*

##### *Joint activities of market surveillance authorities*

1. Market surveillance authorities may agree with other relevant authorities to carry out joint activities aimed at ensuring cybersecurity and protection of consumers with respect to specific products with digital elements placed **on the market** or made available on the market, in particular products **with digital elements** that are often found to present cybersecurity risks.
2. The Commission or ENISA may propose joint activities for checking compliance with this Regulation ~~to be conducted by market surveillance authorities~~ based on indications or information of potential non-compliance across several Member States of products **with digital elements** falling in the scope of this Regulation with the requirements laid down ~~by the latter~~ **herein**.
3. The market surveillance authorities and, **where applicable**, the Commission, ~~where applicable~~, shall ensure that the agreement to carry out joint activities does not lead to unfair competition between economic operators and does not negatively affect the objectivity, independence and impartiality of the parties to the agreement.
4. A market surveillance authority may use any information resulting from the **joint** activities carried out as part of any investigation that it undertakes.
5. The market surveillance authority concerned and, **where applicable**, the Commission, ~~where applicable~~, shall make the agreement on joint activities, including the names of the parties involved, available to the public.

#### *Article 49*

##### *Sweeps*

1. Market surveillance authorities may decide to conduct simultaneous coordinated control actions (“sweeps”) of particular products with digital elements or categories thereof to check compliance with or to detect infringements to this Regulation.
2. Unless otherwise agreed upon by the market surveillance authorities involved, sweeps shall be coordinated by the Commission. The coordinator of the sweep may, where appropriate, make the aggregated results publicly available.
3. ENISA may identify, in the performance of its tasks, including based on the notifications received according to Article 11(1) and (2), categories of products **with digital elements** for which sweeps may be organised. The proposal for sweeps shall be submitted to the ~~potential~~ coordinator referred to in paragraph 2 for the consideration of the market surveillance authorities.

4. When conducting sweeps, the market surveillance authorities involved may use the investigation powers set out Articles 41 to 47 and any other powers conferred upon them by national law.
5. Market surveillance authorities may invite Commission officials, and other accompanying persons authorised by the Commission, to participate in sweeps.



## CHAPTER VI

### DELEGATED POWERS AND COMMITTEE PROCEDURE

#### *Article 50*

##### *Exercise of the delegation*

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in ~~Article 2(4)~~, Article 6(2), ~~Article 6(3)~~, **Article 6a(1)**, Article 6a(25), Article 20(5) and Article 23(5) shall be conferred on the Commission **for a period of five years from ... [date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**
3. The delegation of power referred to in ~~Article 2(4)~~, Article 6(2), ~~Article 6(3)~~, **Article 6a(1)**, Article 6a(25), Article 20(5) and Article 23(5) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with principles laid down in the Inter-institutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to ~~Article 2(4)~~, Article 6(2), ~~Article 6(3)~~, **Article 6a(1)**, Article 6a(25), Article 20(5) and Article 23(5) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### *Article 51*

##### *Committee procedure*

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a committee member so requests.

## CHAPTER VII

### CONFIDENTIALITY AND PENALTIES

#### *Article 52*

#### *Confidentiality*

1. All parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks and activities in such a manner as to protect, in particular:
  - (a) intellectual property rights, and confidential business information or trade secrets of a natural or legal person, including source code, except the cases referred to in Article 5 of Directive 2016/943 of the European Parliament and of the Council<sup>36</sup>;
  - (b) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits;
  - (c) public and national security interests;
  - (d) integrity of criminal or administrative proceedings.
2. Without prejudice to paragraph 1, information exchanged on a confidential basis between the market surveillance authorities and between market surveillance authorities and the Commission shall not be disclosed without the prior agreement of the originating market surveillance authority.
3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law of the Member States.
4. The Commission and Member States may exchange, where necessary, sensitive information with relevant authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements guaranteeing an adequate level of protection.

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<sup>36</sup> Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

## Article 53

### Penalties

1. Member States shall lay down the rules on penalties applicable to infringements ~~by economic operators~~ of this Regulation and shall take all measures necessary to ensure that they are ~~enforced~~ **implemented**. The penalties provided for shall be effective, proportionate and dissuasive.
2. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it without delay of any subsequent amendment affecting them.
3. The non-compliance with the essential cybersecurity requirements laid down in Annex I and the obligations set out in Articles 10 and 11 shall be subject to administrative fines of up to 15 000 000 EUR or, if the offender is an undertaking, up to 2.5 % of the its total worldwide annual turnover for the preceding financial year, whichever is higher.
4. The non-compliance with ~~any other~~ **the obligations set out in Articles [Articles 12; 13; 14; 15; 16; 17; 20; 22 (1)-(4); 23 (1)-(4); 24(1)-(3); 29; 31; 37; 38; 42]** under this Regulation shall be subject to administrative fines of up to 10 000 000 EUR or, if the offender is an undertaking, up to 2 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.
5. The supply of incorrect, incomplete or misleading information to notified bodies and market surveillance authorities in reply to a request shall be subject to administrative fines of up to 5 000 000 EUR or, if the offender is an undertaking, up to 1 % of its total worldwide annual turnover for the preceding financial year, whichever is higher.
6. When deciding on the amount of the administrative fine in each individual case, all relevant circumstances of the specific situation shall be taken into account and due regard shall be given to the following:
  - (a) the nature, gravity and duration of the infringement and of its consequences;
  - (b) whether administrative fines have been already applied by other market surveillance authorities to the same **economic** operator for a similar infringement;
  - (c) the size and market share of the **economic** operator committing the infringement.
7. Market surveillance authorities that apply administrative fines shall ~~share~~ **communicate** this ~~to information with~~ the market surveillance authorities of other Member States through the information and communication system referred to in Article 34 of Regulation (EU) 2019/1020.

8. Each Member State shall lay down rules on whether and to what extent administrative fines may be imposed on public authorities and **public** bodies established in that Member State.
9. Depending on the legal system of the Member States, the rules on administrative fines may be applied in such a manner that the fines are imposed by competent national courts or other bodies according to the competences established at national level in those Member States. The application of such rules in those Member States shall have an equivalent effect.
10. Administrative fines may be imposed, depending on the circumstances of each individual case, in addition to any other corrective or restrictive measures applied by the market surveillance authorities for the same infringement.

## CHAPTER VIII

### TRANSITIONAL AND FINAL PROVISIONS

#### *Article 54*

##### *Amendment to Regulation (EU) 2019/1020*

In Annex I to Regulation (EU) 2019/1020 the following point is added:

'71. [Regulation XXX][Cyber Resilience Act]'.

#### *Article XXX*

##### *Representative actions*

**Directive (EU) 2020/1828 shall apply to the representative actions brought against infringements by economic operators of provisions of this Regulation that harm, or may harm, the collective interests of consumers.**

#### *Article XXX*

##### *Amendment to Directive (EU) 2020/1828*

**In Annex I to Directive (EU) 2020/1828, the following point is added:**

**'(XX) [Regulation XXX][Cyber Resilience Act]'**

#### *Article 55*

##### *Transitional provisions*

1. EU type-examination certificates and approval decisions issued regarding cybersecurity requirements for products with digital elements that are subject to other Union harmonisation legislation shall remain valid until [42 months after the date of entry into force of this Regulation], unless they expire before that date, or unless otherwise specified in other Union legislation, in which case they shall remain valid as referred to in that Union legislation.
2. Products with digital elements that have been placed on the market before [date of application of this Regulation referred to in Article 57], shall be subject to requirements of this Regulation only if, from that date, those products are subject to substantial modifications in their design or intended purpose.

3. By way of derogation from paragraph 2, the obligations laid down in Article 11 shall apply to all products with digital elements within the scope of this Regulation that have been placed on the market before [date of application of this Regulation referred to in Article 57].

*Article 56*

*Evaluation and review*

By [36 months after the date of application of this Regulation] and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.

*Article 57*

*Entry into force and application*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [24 36 months after the date of entry into force of this Regulation]. However Article 11 shall apply from [~~12~~ 24 months after the date of entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

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## ESSENTIAL CYBERSECURITY REQUIREMENTS

1. SECURITY REQUIREMENTS RELATING TO THE PROPERTIES OF PRODUCTS WITH DIGITAL ELEMENTS
  - 1) Products with digital elements shall be designed, developed and produced in such a way that they ~~enable ensure~~ an appropriate level of cybersecurity based on the risks;
  - 2) ~~Products with digital elements shall be delivered without any known exploitable vulnerabilities;~~
  - 3) On the basis of the **cybersecurity** risk assessment referred to in Article 10(2) and where applicable, products with digital elements shall:
    - (aa) **be placed on the market without any known exploitable vulnerabilities;**
      - (a) **be placed on the market ~~delivered~~ with a secure by default configuration, including the possibility to reset the product to its original state, and including a default setting that security updates be installed automatically according to requirements in point (aaa) of this section and Annex II,(9), with a clear and easy- to-use opt-out mechanism.**
      - (aaa) **where applicable under Annex I,1 (3)a of this section, set as a default setting – which can be switched off – that security updates are installed automatically on products with digital elements if not installed within a certain timeframe;**
    - (b) ensure protection from unauthorised access by appropriate control mechanisms, including but not limited to authentication, identity or access management systems;
    - (c) protect the confidentiality of stored, transmitted or otherwise processed data, personal or other, such as by encrypting relevant data at rest or in transit by state of the art mechanisms;
    - (d) protect the integrity of stored, transmitted or otherwise processed data, personal or other, commands, programs and configuration against any manipulation or modification not authorised by the user, as well as report on corruptions;
    - (e) process only data, personal or other, that are adequate, relevant and limited to what is necessary in relation to the intended ~~use~~**purpose** of the product (‘minimisation of data’);
    - (f) protect the availability of essential functions, including the resilience against and mitigation of denial of service attacks;
    - (g) minimise their ~~own~~ negative impact **by themselves or connected devices** on the availability of services provided by other devices or networks;



- (h) be designed, developed and produced to limit attack surfaces, including external interfaces;
- (i) be designed, developed and produced to reduce the impact of an incident using appropriate exploitation mitigation mechanisms and techniques;
- (j) provide security related information by recording and/or monitoring relevant internal activity, including the access to or modification of data, services or functions;
- (k) ~~ensure~~ **enable** that vulnerabilities can be addressed through security updates, including, where applicable, through automatic updates **by default, but with a clear and easy-to-use opt-out mechanism, and where applicable through** the notification of available updates to users, **and the option to temporarily postpone them;**
- (l) **provide the possibility for users to securely and easily remove all data and settings.**

## 2. VULNERABILITY HANDLING REQUIREMENTS

Manufacturers of the products with digital elements shall:

- (1) identify and document vulnerabilities and components contained in the product, including by drawing up a software bill of materials in a commonly used and machine-readable format covering at the very least the top-level dependencies of the product;
- (2) in relation to the risks posed to the products with digital elements, address and remediate vulnerabilities without delay, including by providing security updates;
- (3) apply effective and regular tests and reviews of the security of the product with digital elements;
- (4) once a security update has been made available, publically disclose information about fixed vulnerabilities, including a description of the vulnerabilities, information allowing users to identify the product with digital elements affected, the impacts of the vulnerabilities, their severity and **clear and user friendly** information helping users to remediate the vulnerabilities; **in duly justified cases, where manufacturers consider the security risks of publication to outweigh the security benefits, they may delay making public information regarding a fixed vulnerability until after users have been given the possibility to apply the relevant patch;**
- (5) put in place and enforce a policy on coordinated vulnerability disclosure;
- (6) take measures to facilitate the sharing of information about potential vulnerabilities in their product with digital elements as well as in third party components contained in that product, including by providing a contact

address for the reporting of the vulnerabilities discovered in the product with digital elements;

- (7) **in relation to the cybersecurity risks posed to the products with digital elements**, provide for mechanisms to securely distribute updates for products with digital elements to ensure that ~~exploitable~~ vulnerabilities are fixed or mitigated in a timely **and, where applicable, automatic** manner;
  
- (8) ensure that, where security ~~patches or~~ updates are available to address identified security issues, they are disseminated without delay and free of charge, accompanied by advisory messages providing users with the relevant information, including on potential action to be taken.

## INFORMATION AND INSTRUCTIONS TO THE USER

As a minimum, the product with digital elements shall be accompanied by:

- ~~(1) the name, registered trade name or registered trade mark of the manufacturer, and the postal address, and the email address or other digital contact as well as, where applicable, the website at which the manufacturer can be contacted, on the product or, where that is not possible, on its packaging or in a document accompanying the product;~~
- (2) the **single** point of contact where information about ~~cybersecurity~~ vulnerabilities of the product **with digital elements** can be reported and received;
- (3) **Name and type and any additional information enabling the unique correct** identification of the type, batch, version or serial number or other element allowing the identification of the product and the corresponding instructions and user information;
- (4) the intended **purpose use**, including the security environment provided by the manufacturer, as well as the product's essential functionalities and information about the security properties;
- (5) any known or foreseeable circumstance, related to the use of the product **with** digital elements in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to significant cybersecurity risks;
- ~~(6) if and, where applicable, where the software bill of materials can be accessed;~~
- ~~(7) where applicable, the internet address at which the full EU declaration of conformity can be accessed;~~
- (8) the type of technical security support offered by the manufacturer, **expected product lifetime and end-date** and until when **it the technical security support** will be provided, at the very least until when users can expect to receive security updates;
- (9) detailed instructions or, **where applicable**, an internet address referring to such detailed instructions and information on:
  - (a) the necessary measures during initial commissioning and throughout the lifetime of the product to ensure its secure use;
  - (b) how changes to the product can affect the security of data;
  - (c) how security-relevant updates can be installed;
  - (d) the secure decommissioning of the product, including information on how user data can be securely removed;
  - (e) **how the default setting of automatically installed updates, as required by point (aaa) of section 1.3 of Annex I, can be turned off.**

- (xx) If the manufacturer decides to make available the software bill of materials to the user, the information and instructions to the user accompanying the product with digital elements shall also include that software bill of materials as set out in Section 2, point (1) of Annex I.**

## CLASSES AND CATEGORIES OF ~~CRITICAL~~ PRODUCTS WITH DIGITAL ELEMENTS

Class I

**Categories of products with digital elements which meet the criteria referred to in Article 6(2), point (a):**

- ~~1. Identity management systems software and privileged access management software;~~
- ~~2. Standalone and embedded browsers;~~
- ~~3. Password managers;~~
- 1. 4. Software that searches for, removes, or quarantines malicious software;**
- ~~5. Products with digital elements with the function of virtual private network (VPN);~~
- ~~6. Network management systems;~~
- ~~7. Network configuration management tools;~~
- ~~8. Network traffic monitoring systems for throughput and flow control;~~
- ~~9. Management of network resources;~~
- 2. 3. 10. Security information and event management (SIEM) systems;**
- 3. 11. Update/patch management, including General purpose boot managers;**
- 4. 17. Firewalls, intrusion detection and/or prevention systems not covered by class II;**
- 5. 3. Public key infrastructure and digital certificate issuance software;**
- 6. Smart home products with safety functionalities, such as door locks and alarm systems.**
- ~~12. Application configuration management systems;~~
- ~~13. Remote access/sharing software;~~
- ~~14. Mobile device management software;~~
- ~~15. Physical network interfaces;~~

Categories of products with digital elements which meet the criteria referred to in Article 6(2), point (b):

~~1. General purpose Operating systems not covered by class II;~~

~~17. Firewalls, intrusion detection and/or prevention systems not covered by class II;~~

~~2. 9. Network Management Software of network resources, including (SDN) controllers;~~

~~3. 12. Application configuration management systems for centralised systems configuration;~~

~~4. 13. Remote access/sharing software;~~

~~4a. Remote desktop sharing software;~~

~~5. 14. Mobile device management software for the configuration, monitoring and updating of mobile devices;~~

~~6. 15. Physical and virtual network interfaces;~~

~~7. 18. Routers, modems intended for the connection to the internet, and switches, intended for industrial use~~

~~8. Microprocessors not covered by class II;~~

~~9. Microcontrollers;~~

~~21. Application specific integrated circuits (ASIC) and field programmable gate arrays (FPGA) intended for the use by essential entities of the type referred to in [Annex I to the Directive XXX/XXXX (NIS2)];~~

~~10. 22. Products that are intended for use in Industrial Automation & Control Systems (IACS), such as programmable logic controllers (PLC), distributed control systems (DCS), computerised numeric controllers for machine tools (CNC) and supervisory control and data acquisition systems (SCADA);~~

~~23. Industrial Internet of Things not covered by class II;~~

~~11. Application specific integrated circuits (ASIC) and field programmable gate arrays (FPGA)~~

Class II

Categories of products with digital elements which meet both criteria referred to in Article 6(2), points (a) and (b):

1. Operating systems for servers, desktops, and mobile devices;

~~1. Identity management systems software and privileged access management software;~~

~~2. Authentication software, including password managers;~~

3. Products with digital elements that support virtual private network (VPN) functions such as VPN server and clients;

~~4. 6. Network management systems for the configuration, monitoring and updating of network devices;~~

5.-2. Hypervisors and container runtime systems that support virtualised execution of operating systems and similar environments;

3. Public key infrastructure and digital certificate issuers;

4. Firewalls, intrusion detection and/or prevention systems intended for industrial use;

5. General purpose microprocessors;

6. Microprocessors intended for integration in programmable logic controllers and secure elements;

7. Routers, modems intended for the connection to the internet, and switches, intended for industrial use;

~~8. Devices based on tamper-resistant integrated circuits, including embedded and integrated Secure Elements;~~

9. Hardware Security Modules (HSMs);

10. Secure cryptoprocessors;

11. Smartcards, smartcard readers and tokens.

6. 4. Firewalls, intrusion detection and/or prevention systems intended for industrial use.

~~21. Application specific integrated circuits (ASIC) and field programmable gate arrays (FPGA) intended for the use by essential entities of the type referred to in [Annex I to the Directive XXX/XXXX (NIS2)];~~

14. — Robot sensing and actuator components and robot controllers;

~~12. 15. Smart meters as defined in Article 2(23) of Directive (EU) 2019/944.]~~

**Categories of highly critical products with digital elements**

1. ~~Devices based on tamper-resistant integrated circuits, including embedded and integrated Secure Elements;~~
2. Hardware Devices with Security Boxes, including Hardware Security Modules (HSMs);
3. The core security functionalities of smart metering systems as defined in Article 2(23) of Directive (EU) 2019/944 and other embedded devices for advanced security purposes, including for sSecure cryptoprocessøring and secure data sharing;
4. Smartcards or similar devices, smartcard readers and tokens, including Secure Elements.



**Simplified EU declaration of conformity**

**The simplified EU declaration of conformity referred to in Article [10(11)] shall be provided as follows:**

**Hereby, [Name of manufacturer] declares that the product with digital elements type [designation of type of product with digital element] is in compliance with Regulation XX.**

**The full text of the EU declaration of conformity is available at the following internet address:**

**EU DECLARATION OF CONFORMITY**

The EU declaration of conformity referred to in Article 20, shall contain all of the following information:

1. Name and type and any additional information enabling the unique identification of the product with digital elements;
2. Name and address of the manufacturer or his authorised representative;
3. A statement that the EU declaration of conformity is issued under the sole responsibility of the provider;
4. Object of the declaration (identification of the product allowing traceability. It may include a photograph, where appropriate);
5. A statement that the object of the declaration described above is in conformity with the relevant Union harmonisation legislation;
6. References to any relevant harmonised standards used or any other common specification or cybersecurity certification in relation to which conformity is declared;
7. Where applicable, the name and number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate issued;
8. Additional information:

Signed for and on behalf of: .....

(place and date of issue):

(name, function) (signature):

## CONTENTS OF THE TECHNICAL DOCUMENTATION

The technical documentation referred to in Article 23 shall contain at least the following information, as applicable to the relevant product with digital elements:

1. a general description of the product with digital elements, including:
  - (a) its intended purpose;
  - (b) versions of software affecting compliance with essential requirements;
  - (c) where the product with digital elements is a hardware product, photographs or illustrations showing external features, marking and internal layout;
  - (d) user information and instructions as set out in Annex II;
2. a description of the design, development and production of the product and vulnerability handling processes, including:
  - (a) complete information on the design and development of the product with digital elements, including, where applicable, drawings and schemes and/or a description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing;
  - (b) complete information and specifications of the vulnerability handling processes put in place by the manufacturer, including the software bill of materials, the coordinated vulnerability disclosure policy, evidence of the provision of a contact address for the reporting of the vulnerabilities and a description of the technical solutions chosen for the secure distribution of updates;
  - (c) complete information and specifications of the production and monitoring processes of the product with digital elements and the validation of these processes.
3. an assessment of the cybersecurity risks against which the product with digital elements is designed, developed, produced, delivered and maintained as laid down in Article 10 of this Regulation;

4. a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, common specifications as set out in Article 19 of this Regulation or cybersecurity certification schemes under Regulation (EU) 2019/881 pursuant to Article 18(3), and, where those harmonised standards, common specifications or cybersecurity certification schemes have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Sections 1 and 2 of Annex I, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, common specifications or cybersecurity certifications, the technical documentation shall specify the parts which have been applied;
5. reports of the tests carried out to verify the conformity of the product and of the vulnerability handling processes with the applicable essential requirements as set out in Sections 1 and 2 of Annex I;
6. a copy of the EU declaration of conformity;
7. where applicable, the software bill of materials as defined in Article 3, point (36), further to a reasoned request from a market surveillance authority provided that it is necessary in order for this authority to be able to check compliance with the essential requirements set out in Annex I.

## CONFORMITY ASSESSMENT PROCEDURES

### Conformity Assessment procedure based on internal control (based on Module A)

1. Internal control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on its sole responsibility that the products with digital elements satisfy all the essential requirements set out in Section 1 of Annex I and the manufacturer meets the essential requirements set out in Section 2 of Annex I.

2. The manufacturer shall draw up the technical documentation described in Annex V.

3. Design, development, production and vulnerability handling of products with digital elements

The manufacturer shall take all measures necessary so that the design, development, production and vulnerability handling processes and their monitoring ensure compliance of the manufactured or developed products with digital elements and of the processes put in place by the manufacturer with the essential requirements set out in sections 1 and 2 of Annex I.

4. Conformity marking and declaration of conformity

4.1. The manufacturer shall affix the CE to each individual product with digital elements that satisfies the applicable requirements of this Regulation.

4.2. The manufacturer shall draw up a written EU declaration of conformity for each product with digital elements in accordance with Article 20 and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product with digital elements has been placed on the market. The EU declaration of conformity shall identify the product with digital elements for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representatives

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## **EU-type examination (based on Module B)**

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design and development of a product and the vulnerability handling processes put in place by the manufacturer, and attests that a product with digital elements meets the essential requirements set out in Section 1 of Annex I and that the manufacturer meets the essential requirements set out in Section 2 of Annex I.
2. EU-type examination shall be carried out by assessment of the adequacy of the technical design and development of the product through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens of one or more critical parts of the product (combination of production type and design type).
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- a written declaration that the same application has not been lodged with any other notified body;
- the technical documentation, which shall make it possible to assess the product's conformity with the applicable essential requirements as set out in Section 1 of Annex I and the manufacturer's vulnerability handling processes set out in Section 2 of Annex I, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain, wherever applicable, at least the elements set out in Annex V;
- the supporting evidence for the adequacy of the technical design and development solutions and vulnerability handling processes. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:
  - 4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design and development of the product with the essential requirements set out in Section 1 of Annex I and of the vulnerability handling processes put in place by the manufacturer with the essential requirements set out in Section 2 of Annex I;

- 4.2. verify that the specimen(s) have been developed or manufactured in conformity with the technical documentation, and identify the elements which have been designed and developed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed and developed without applying the relevant provisions of those standards;
- 4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications for the requirements set out in Annex I, these have been applied correctly;
- 4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications for the requirements set out in Annex I have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements;
- 4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.
5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
6. Where the type and the vulnerability handling processes meet the essential requirements set out in Annex I, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type and vulnerability handling processes. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured or developed products with the examined type and vulnerability handling processes to be evaluated and to allow for in-service control.

Where the type and the vulnerability handling processes do not satisfy the applicable essential requirements set out in Annex I, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type and the vulnerability handling processes may no longer comply with the applicable essential requirements set out in Annex I to this Regulation, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type and the vulnerability handling processes that may affect the conformity with the essential requirements set out in Annex I, or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authorities concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

### **Conformity to type based on internal production control (based on Module C)**

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the products concerned are in conformity with the type described in the EU-type examination certificate and satisfy the essential requirements set out in Section 1 of Annex I **and that the manufacturer meets the essential requirements set out in Section 2 of Annex I.**
2. Production
  - 2.1. The manufacturer shall take all measures necessary so that the production and its monitoring ensure conformity of the manufactured products with the approved type described in the EU-type examination certificate and with the essential requirements as set out in Section 1 of Annex I **and ensures that the manufacturer meets the essential requirements set out in Section 2 of Annex I.**
3. Conformity marking and declaration of conformity
  - 3.1. The manufacturer shall affix the CE marking to each individual product that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of the legislative instrument.



3.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up. A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

### **Conformity based on full quality assurance (based on Module H)**

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products (or product categories) concerned satisfy the essential requirements set out in Section 1 of Annex I, and that the vulnerability handling processes put in place by the manufacturer meet the requirements set out in Section 2 of Annex I.

2. Design, development, production and vulnerability handling of products with digital elements

The manufacturer shall operate an approved quality system as specified in point 3 for the design, development, and production of the products concerned and for handling vulnerabilities, maintain its effectiveness throughout the lifecycle of the products concerned, and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- the technical documentation for one model of each category of products intended to be manufactured or developed. The technical documentation shall, wherever applicable, contain at least the elements as set out in Annex V;
- the documentation concerning the quality system; and
- a written declaration that the same application has not been lodged with any other notified body.

- 3.2. The quality system shall ensure compliance of the products with the essential requirements set out in Section 1 of Annex I and compliance of the vulnerability handling processes put in place by the manufacturer with the requirements set out in Section 2 of Annex I.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design, development, product quality and vulnerability handling;
- the technical design and development specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements set out in Section 1 of Annex I that apply to the products will be met;
- the procedural specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements set out in Section 2 of Annex I that apply to the manufacturer will be met;
- the design and development control, as well as design and development verification techniques, processes and systematic actions that will be used when designing and developing the products pertaining to the product category covered;
- the corresponding production, quality control and quality assurance techniques, processes and systematic actions that will be used;
- the examinations and tests that will be carried out before, during and after production, and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc;
- the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Regulation. The audit shall include an assessment visit to the manufacturer's premises, where such premises exist. The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, development, production, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

- the quality system documentation;
- the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;
- the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

5. Conformity marking and declaration of conformity

- 5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that satisfies the requirements set out in Section 1 of Annex I to this Regulation.
- 5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:
  - the technical documentation referred to in point 3.1;
  - the documentation concerning the quality system referred to in point 3.1;
  - the change referred to in point 3.5, as approved;
  - the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.
7. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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