

NIST IR 8477-Based Set Theory Relationship Mapping (STRM)

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FDE #	FDE Name	Focal Document Element (FDE) Description	STRM Rationale	STRM Relationship	SCF Control	SCF #	Secure Controls Framework (SCF) Control Description	Strength of Relationship	Notes
Article 1	Subject matter	This Regulation lays down:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 1(a)	N/A	rules for the placing on the market of products with digital elements to ensure the cybersecurity of such products;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 1(b)	N/A	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;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 1(c)	N/A	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;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 1(d)	N/A	rules on market surveillance and enforcement of the above-mentioned rules and requirements.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 2	Scope	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 2.1	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 2.2	N/A	This Regulation does not apply to products with digital elements to which the following Union acts apply:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 2.2(a)	N/A	Regulation (EU) 2017/745;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 2.2(b)	N/A	Regulation (EU) 2017/746;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 2.2(c)	N/A	Regulation (EU) 2019/2144.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 2.3	N/A	This Regulation does not apply to products with digital elements that have been certified in accordance with Regulation (EU) 2018/1139.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 2.4	N/A	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: End - 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 2.4(a)	N/A	such limitation or exclusion is consistent with the overall regulatory framework applying to those products; and	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 2.4(b)	N/A	the said rules achieve the same level of protection as the one provided for by this Regulation.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 2.5	N/A	This Regulation does not apply to products with digital elements developed exclusively for national security or military purposes or to products specifically designed to process classified information.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 3	Definitions	[see regulation for specific definitions]	Functional	Subset Of	Standardized Terminology	SEA-02.1	Mechanisms exist to standardize technology and process terminology to reduce confusion amongst groups and departments.	10	
Article 4	Free movement	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 4.1	N/A	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	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 4.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 4.3	N/A	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	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 5	Requirements for products with digital elements	Products with digital elements shall only be made available on the market where: 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	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 5.1	N/A		Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 5.2	N/A	the processes put in place by the manufacturer comply with the essential requirements set out in Section 2 of Annex I.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 6	Critical products with digital elements	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.1	N/A	Products with digital elements that belong to a category which is listed in Annex III shall be considered critical products with digital elements. Products which have the core functionality of a category that is listed in Annex III to this Regulation shall be considered as falling into that category. Categories of critical products with digital elements shall be divided into class I and class II as set out in Annex III, reflecting the level of cybersecurity risk related to these products.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.2	N/A	The Commission is empowered to adopt delegated acts in accordance with Article 50 to amend Annex III by including in the list of categories of critical products with digital elements a new category 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 level of cybersecurity risk related to the category of products with digital elements. In determining the level of cybersecurity risk, one or several of the following criteria shall be taken into account:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.2(a)	N/A	the cybersecurity-related functionality of the product with digital elements, and whether the product with digital elements has at least one of the following attributes:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.2(a)(i)	N/A	it is designed to run with elevated privilege or manage privileges;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.2(a)(ii)	N/A	it has direct or privileged access to networking or computing resources;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.2(a)(iii)	N/A	it is designed to control access to data or operational technology;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.2(a)(iv)	N/A	it performs a function critical to trust, in particular security functions such as network control, endpoint security, and network protection.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.2(b)	N/A	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/XXX/NS2];	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.2(c)	N/A	the intended use of performing critical or sensitive functions, such as processing of personal data;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.2(d)	N/A	the potential extent of an adverse impact, in particular in terms of its intensity and its ability to affect a plurality of persons;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.2(e)	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.3	N/A	The Commission is empowered to adopt a delegated act in accordance with Article 50 to supplement this Regulation by specifying the definitions of the product categories under class I and class II as set out in Annex III. The delegated act shall be adopted [by 12 months since the entry into force of this Regulation].	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.4	N/A	Critical products with digital elements shall be subject to the conformity assessment procedures referred to in Article 24(2) and (3).	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.5	N/A	The Commission is empowered to adopt delegated acts in accordance with Article 50 to 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, the Commission shall take into account 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:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.5(a)	N/A	used or relied upon by the essential entities of the type referred to in Annex (Annex I) to the Directive [Directive XXX/XXX/NS2] or will have potential future significance for the activities of these entities; or	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 6.5(b)	N/A	relevant for the resilience of the overall supply chain of products with digital elements against disruptive events	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 7	General product safety	By way of derogation from Article 2(1), third subparagraph, point (b), of Regulation (General Product Safety Regulation) where products with digital elements are not subject to specific requirements laid down in other Union harmonisation legislation within the meaning of Article 3, point (25) of the General Product Safety Regulation), 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 8	General product safety	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 8.1	N/A	Products with digital elements classified as high-risk AI systems in accordance with Article [Article 6] of Regulation (the AI Regulation) which fall within the scope of this 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 requirements related to cybersecurity set out in Article [Article 15] of 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	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control

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Article 8.2	N/A	For the products 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 to control the conformity of the high-risk AI systems under the Regulation [AI Regulation] shall be also entitled to control the conformity of the high-risk AI systems within the scope of this Regulation with the requirements set out in Annex I to the Regulation provided that the compliance of those notified bodies with the requirements laid down in Article 29 of this Regulation have been assessed in the context of the notification procedure under Regulation [AI Regulation].	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 8.3	N/A	By derogation from paragraph 2, critical products with digital elements listed in Annex III of this Regulation, which have to apply the conformity assessment procedures referred to in Articles 24(2)(a), 24(2)(b), 24(3)(a) and 24(3)(b) under this Regulation and which are also classified as high-risk AI systems according to Article 6 of the Regulation [AI Regulation] and to which the conformity assessment procedure based on internal control referred to in Annex I to the Regulation [AI Regulation] apply shall be subject to the conformity assessment procedures as required by this Regulation in so far as the essential requirements of this Regulation are concerned.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
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 essential health and safety requirements set out in 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 the achievement of the level of protection required by those requirements is demonstrated in the EU declaration of conformity issued under this Regulation.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 10	Obligations of manufacturers	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 10.1	N/A	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.	Functional	Intersects With	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	5	
Article 10.1	N/A	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.	Functional	Intersects With	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	5	
Article 10.2	N/A	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.	Functional	Intersects With	Conformity Assessment	CPA-01.4	Mechanisms exist to conduct assessments to demonstrate security, compliance and/or resilience capability conformity with applicable cybersecurity and data protection laws, regulations and/or contractual obligations.	5	
Article 10.3	N/A	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.	Functional	Intersects With	Product-Specific Risk Assessment Artifacts	TDA-22.1	Mechanisms exist to include a detailed cybersecurity risk assessment in the technical documentation for Technology Assets, Applications and/or Services (TAAS) to demonstrate applicable risks in approved use cases.	5	
Article 10.4	N/A	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. They shall ensure that such components do not compromise the security of the product with digital elements.	Functional	Subset Of	Supply Chain Risk Management (SCRM)	TPM-03	Mechanisms exist to: (1) Evaluate security risks and threats associated with Technology Assets, Applications and/or Services (TAAS) supply chains; and (2) Take appropriate remediation actions to minimize the organization's exposure to those risks and threats, as necessary.	10	
Article 10.5	N/A	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 become aware of and any relevant information provided by third parties, and, where applicable, update the risk assessment of the product.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 10.6	N/A	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 that vulnerabilities of that product are handled effectively and in accordance with the essential requirements set out in Section 2 of Annex I. 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.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 10.6	N/A	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 that vulnerabilities of that product are handled effectively and in accordance with the essential requirements set out in Section 2 of Annex I. 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.	Functional	Subset Of	Ongoing Product Security Support	TDA-02.9	Mechanisms exist to deliver security updates to Technology Assets, Applications and/or Services (TAAS), where applicable, through: (1) Automatic updates; and (2) Notification of available updates to affected users.	10	
Article 10.7	N/A	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.	Functional	Intersects With	Conformity Assessment	CPA-01.4	Mechanisms exist to conduct assessments to demonstrate security, compliance and/or resilience capability conformity with applicable cybersecurity and data protection laws, regulations and/or contractual obligations.	8	
Article 10.7	N/A	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.	Functional	Intersects With	Technical Documentation Artifacts	TDA-22	Mechanisms exist to generate appropriate technical documentation artifacts for Technology Assets, Applications and/or Services (TAAS) in sufficient detail to demonstrate conformity with applicable statutory, regulatory and contractual compliance requirements.	8	
Article 10.8	N/A	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.	Functional	Subset Of	Media & Data Retention	DCH-18	Mechanisms exist to retain media and data in accordance with applicable statutory, regulatory and contractual obligations.	10	
Article 10.9	N/A	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. 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 19 by reference to which the conformity of the product with digital elements is declared or by application of which its conformity is verified.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 10.10	N/A	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 in a language which can be easily understood by users. They shall be clear, understandable, intelligible and legible. They shall allow for a secure installation, operation and use of the products with digital elements.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 10.11	N/A	Manufacturers shall either provide the EU declaration of conformity with the product with digital elements or include in the instructions and information set out in Annex II the internet address at which the EU declaration of conformity can be accessed.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 10.12	N/A	From the placing on the market and for the 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.	Functional	Intersects With	Corrective Action	CPA-02.3	Mechanisms exist to take corrective action to remediate instances of non-conformity with applicable statutory, regulatory, and/or contractual compliance obligations.	8	
Article 10.12	N/A	From the placing on the market and for the 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.	Functional	Subset Of	Product Conformity Governance	TDA-21	Mechanisms exist to ensure developed Technology Assets, Applications and/or Services (TAAS) conform to applicable statutory and regulatory requirements, based on the product's and/or service's: (1) Use case(s); and (2) Geographic markets.	10	

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Article 10.13	N/A	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 the cybersecurity risks posed by the product with digital elements, which they have placed on the market.	Functional	Intersects With	Ability To Demonstrate Conformity	CPL-01.3	Mechanisms exist to ensure the organization is able to demonstrate security, compliance and/or resilience capability conformity with applicable cybersecurity and data protection laws, regulations and/or contractual obligations.	5	
Article 10.14	N/A	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 ceasing 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 10.15	N/A	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).	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 11	Reporting obligations of manufacturers	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 11.1	N/A	The manufacturer shall, without undue delay 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/XXX (NIS2)] of Member States concerned upon receipt and inform the market surveillance authority about the notified vulnerability.	Functional	Intersects With	Reporting Exploitable Vulnerabilities	TDA-02.13	Mechanisms exist to notify applicable stakeholders about potentially exploitable vulnerabilities in organization-developed Technology Assets, Applications and/or Services (TAAS), as required by statutory, regulatory and/or contractual obligations.	8	
Article 11.2	N/A	The manufacturer shall, without undue delay and in any event within 24 hours of becoming aware of it, notify to ENISA any incident having impact on the security of the product with digital elements. ENISA shall, without undue delay, unless for justified cybersecurity risk-related grounds, forward the notifications to the single point of contact designated in accordance with Article [Article X] of Directive [Directive XXX/XXX (NIS2)] of the Member States concerned and inform the market surveillance authority about the notified incidents. The incident notification shall include information on the severity and impact of the incident and, where applicable, indicate whether the manufacturer suspects the incident to be caused by unlawful or malicious acts or considers it to have a cross-border impact.	Functional	Intersects With	Serious Incident Reporting	IRO-10.5	Mechanisms exist to report any serious incident involving the organization's Technology Assets, Applications, Services and/or Data (TAASD) to relevant authorities in the locality where the incident occurred, in accordance with mandatory reporting: (1) Requirements; and (2) Timelines.	5	
Article 11.3	N/A	ENISA shall submit to the European cyber crisis liaison organisation network (EUCYCLONE) established by Article [Article X] of Directive [Directive XXX/XXX (NIS2)] information notified pursuant to paragraphs 1 and 2 if such information is relevant for the coordinated management of large-scale cybersecurity incidents and crises at an operational level.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 11.4	N/A	The manufacturer shall inform, without undue delay and after becoming aware, the users of the product with digital elements about the incident and, where necessary, about corrective measures that the user can deploy to mitigate the impact of the incident.	Functional	Intersects With	Serious Incident Reporting	IRO-10.5	Mechanisms exist to report any serious incident involving the organization's Technology Assets, Applications, Services and/or Data (TAASD) to relevant authorities in the locality where the incident occurred, in accordance with mandatory reporting: (1) Requirements; and (2) Timelines.	5	
Article 11.5	N/A	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 and 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 51(2).	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 11.6	N/A	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 referred to in Article [Article X] of Directive [NIS2]. The first such report shall be submitted within 24 months after the obligations laid down in paragraphs 1 and 2 start applying.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 11.7	N/A	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.	Functional	Intersects With	Disclosure of Vulnerabilities	TDA-02.11	Mechanisms exist to disclose information about vulnerabilities to relevant stakeholders, including: (1) A description of the vulnerability(ies); (2) Affected product(s) and/or service(s); (3) Potential impact of the vulnerability(ies); (4) Severity of the vulnerability(ies); and (5) Guidance to remediate the vulnerability(ies).	5	
Article 11.7	N/A	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.	Functional	Intersects With	Software Bill of Materials (SBOM)	TDA-04.2	Mechanisms exist to generate, or obtain, a Software Bill of Materials (SBOM) for Technology Assets, Applications and/or Services (TAAS) that lists software packages in use, including versions and applicable licenses.	8	
Article 12	Authorised representatives	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 12.1	N/A	A manufacturer may appoint an authorised representative by a written mandate.	Functional	Intersects With	Localized Representation	CPL-08	Mechanisms exist to appoint localized representation with a physical presence in localities, as required by applicable laws and/or regulators.	8	
Article 12.2	N/A	The obligations laid down in Article 10(1) to (7) first indent and (9) shall not form part of the authorised representative's mandate.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 12.3	N/A	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:	Functional	Intersects With	Representative Powers	CPL-08.1	Mechanisms exist to contract localized representation to perform specified functions in regard to representing statutory and/or regulatory compliance matters.	8	
Article 12.3(a)	N/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;	Functional	Intersects With	Representative Powers	CPL-08.1	Mechanisms exist to contract localized representation to perform specified functions in regard to representing statutory and/or regulatory compliance matters.	8	
Article 12.3(b)	N/A	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;	Functional	Intersects With	Representative Powers	CPL-08.1	Mechanisms exist to contract localized representation to perform specified functions in regard to representing statutory and/or regulatory compliance matters.	8	
Article 12.3(c)	N/A	cooperate with the market surveillance authorities, at their request, on any action taken to eliminate the risks posed by a product with digital elements covered by the authorised representative's mandate.	Functional	Intersects With	Representative Powers	CPL-08.1	Mechanisms exist to contract localized representation to perform specified functions in regard to representing statutory and/or regulatory compliance matters.	8	
Article 13	Obligations of importers	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 13.1	N/A	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 that have been brought into place by the manufacturer are compliant with the essential requirements set out in Section 2 of Annex I.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 13.2	N/A	Before placing a product with digital elements on the market, importers shall ensure that:	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 13.2(a)	N/A	the appropriate conformity assessment procedures referred to in Article 24 have been carried out by the manufacturer;	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 13.2(a)	N/A	the appropriate conformity assessment procedures referred to in Article 24 have been carried out by the manufacturer;	Functional	Intersects With	Conformity Assessment	CPL-01.4	Mechanisms exist to conduct assessments to demonstrate security, compliance and/or resilience capability conformity with applicable cybersecurity and data protection laws, regulations and/or contractual obligations.	8	
Article 13.2(b)	N/A	the manufacturer has drawn up the technical documentation;	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 13.2(b)	N/A	the manufacturer has drawn up the technical documentation;	Functional	Subset Of	Technical Documentation Artifacts	TDA-22	Mechanisms exist to generate appropriate technical documentation artifacts for Technology Assets, Applications and/or Services (TAAS) in sufficient detail to demonstrate conformity with applicable statutory, regulatory and contractual compliance requirements.	10	
Article 13.2(c)	N/A	the product with digital elements bears the CE marking referred to in Article 22 and is accompanied by the information and instructions for use as set out in Annex II.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 13.3	N/A	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.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 13.4	N/A	Importers shall indicate their name, registered trade name or registered trademark, the postal address and the email address 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.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	

FDE #	FDE Name	Focal Document Element (FDE) Description	STRM Rationale	STRM Relationship	SCF Control	SCF #	Secure Controls Framework (SCF) Control Description	Strength of Relationship	Notes
Article 13.5	N/A	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	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 13.6	N/A	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.	Functional	Intersects With	Corrective Action	CP-02.3	Mechanisms exist to take corrective action to remediate instances of non-conformity with applicable statutory, regulatory, and/or contractual compliance obligations.	8	
Article 13.6	N/A	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.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 13.7	N/A	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.	Functional	Subset Of	Media & Data Retention	DCH-1B	Mechanisms exist to retain media and data in accordance with applicable statutory, regulatory and contractual obligations.	10	
Article 13.8	N/A	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 taken to eliminate the cybersecurity risks posed by a product with digital elements, which they have placed on the market.	Functional	Subset Of	Assessor Access	CP-03.3	Mechanisms exist to grant assessors minimum necessary access to conduct conformity assessments, including: (1) Logical access to design, development, production, inspection and testing artifacts; and (2) Physical access to facilities.	10	
Article 13.9	N/A	When the importer of a product with digital elements becomes aware that the manufacturer of that product ceased its operations and, as a 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	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 14	Obligations of distributors	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 14.1	N/A	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.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 14.2	N/A	Before making a product with digital elements available on the market, distributors shall verify that:	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 14.2(a)	N/A	the product with digital elements bears the CE marking;	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 14.2(b)	N/A	the manufacturer and the importer have complied with the obligations set out respectively in Articles 10(10), 10(11) and 13(4).	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 14.3	N/A	Where a distributor considers or has reason to believe that a product with digital elements or the processes put in place by its 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 the manufacturer and the market surveillance authorities to that effect.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 14.4	N/A	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.	Functional	Intersects With	Corrective Action	CP-02.3	Mechanisms exist to take corrective action to remediate instances of non-conformity with applicable statutory, regulatory, and/or contractual compliance obligations.	8	
Article 14.4	N/A	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.	Functional	Subset Of	Product Management	TDA-01.1	Mechanisms exist to design and implement product management processes to proactively govern the design, development and production of Technology Assets, Applications and/or Services (TAAS) across the System Development Life Cycle (SDLC) to: (1) Improve functionality; (2) Enhance security and resiliency capabilities; (3) Correct security deficiencies; and (4) Conform with applicable statutory, regulatory and/or contractual obligations.	10	
Article 14.5	N/A	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.	Functional	Subset Of	Assessor Access	CP-03.3	Mechanisms exist to grant assessors minimum necessary access to conduct conformity assessments, including: (1) Logical access to design, development, production, inspection and testing artifacts; and (2) Physical access to facilities.	10	
Article 14.6	N/A	When the distributor of a product with digital elements becomes aware that the manufacturer of that product ceased its operations and, as a result, is not able to comply with the obligations laid down in this Regulation, the distributor 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 17	Identification of economic operators	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 17.1	N/A	Economic operators shall, on request and where the information is available, provide to the market surveillance authorities the following information:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 17.1(a)	N/A	name and address of any economic operator who has supplied them with a product with digital elements;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 17.1(b)	N/A	name and address of any economic operator to whom they have supplied a product with digital elements;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control

FDE #	FDE Name	Focal Document Element (FDE) Description	STRM Rationale	STRM Relationship	SCF Control	SCF #	Security Controls Framework (SCF) Control Description	Strength of Relationship	Notes
Article 17.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 18	Presumption of conformity	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 18.1	N/A	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 covered by those standards or parts thereof, set out in Annex I.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 18.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 18.3	N/A	Products with digital elements and processes put in place by the manufacturer for which an EU statement of conformity or certificate has been issued under a European cybersecurity certification scheme adopted as per Regulation (EU) 2019/891 and specified as per paragraph 4, shall be presumed to be in conformity with the essential requirements set out in Annex I in so far as the EU statement of conformity or cybersecurity certificate, or parts thereof, cover those requirements.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 18.4	N/A	The Commission is empowered, by means of implementing acts, to specify the European cybersecurity certification schemes adopted pursuant to Regulation (EU) 2019/891 that can be used to demonstrate conformity with the essential requirements or parts thereof as set out in Annex I. Furthermore, where applicable, the Commission shall specify if 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).	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
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).	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 20	EU declaration of conformity	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 20.1	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 20.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 20.3	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 20.4	N/A	By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the veracity of the product.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 20.5	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 22	Rules and conditions for affixing the CE marking	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 22.1	N/A	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 to the 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 22.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 22.3	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 22.4	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 22.5	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 22.6	N/A	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).	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 23	Technical documentation	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 23.1	N/A	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.	Functional	Subset Of	Technical Documentation Artifacts	TDA-22	Mechanisms exist to generate appropriate technical documentation artifacts for Technology Assets, Applications and/or Services (TAAS) in sufficient detail to demonstrate conformity with applicable statutory, regulatory and contractual compliance requirements.	10	
Article 23.2	N/A	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.	Functional	Subset Of	Technical Documentation Artifacts	TDA-22	Mechanisms exist to generate appropriate technical documentation artifacts for Technology Assets, Applications and/or Services (TAAS) in sufficient detail to demonstrate conformity with applicable statutory, regulatory and contractual compliance requirements.	10	
Article 23.3	N/A	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.	Functional	Subset Of	Technical Documentation Artifacts	TDA-22	Mechanisms exist to generate appropriate technical documentation artifacts for Technology Assets, Applications and/or Services (TAAS) in sufficient detail to demonstrate conformity with applicable statutory, regulatory and contractual compliance requirements.	10	
Article 23.4	N/A	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.	Functional	Subset Of	Technical Documentation Artifacts	TDA-22	Mechanisms exist to generate appropriate technical documentation artifacts for Technology Assets, Applications and/or Services (TAAS) in sufficient detail to demonstrate conformity with applicable statutory, regulatory and contractual compliance requirements.	10	
Article 23.5	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 24	Conformity assessment procedures for products with digital elements	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 24.1	N/A	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 of the following procedures:	Functional	Intersects With	Conformity Assessment	CPL-01.4	Mechanisms exist to conduct assessments to demonstrate security, compliance and/or resilience capability conformity with applicable cybersecurity and data protection laws, regulations and/or contractual obligations.	8	
Article 24.1(a)	N/A	the internal control procedure (based on module A) set out in Annex V; or	Functional	Intersects With	Conformity Assessment	CPL-01.4	Mechanisms exist to conduct assessments to demonstrate security, compliance and/or resilience capability conformity with applicable cybersecurity and data protection laws, regulations and/or contractual obligations.	8	
Article 24.1(b)	N/A	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	Functional	Intersects With	Conformity Assessment	CPL-01.4	Mechanisms exist to conduct assessments to demonstrate security, compliance and/or resilience capability conformity with applicable cybersecurity and data protection laws, regulations and/or contractual obligations.	8	
Article 24.1(c)	N/A	conformity assessment based on full quality assurance (based on module H) set out in Annex VI.	Functional	Intersects With	Conformity Assessment	CPL-01.4	Mechanisms exist to conduct assessments to demonstrate security, compliance and/or resilience capability conformity with applicable cybersecurity and data protection laws, regulations and/or contractual obligations.	8	
Article 24.2	N/A	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 of the following procedures:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 24.2(a)	N/A	EU-type examination procedure (based on module B) provided for in Annex VI followed by conformity to EU-type based on internal production control (based on module C) set out in Annex VI; or	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 24.2(b)	N/A	conformity assessment based on full quality assurance (based on module H) set out in Annex VI.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 24.3	N/A	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 of the following procedures:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control

FDE #	FDE Name	Focal Document Element (FDE) Description	STRM Rationale	STRM Relationship	SCF Control	SCF #	Security Controls Framework (SCF) Control Description	Strength of Relationship	Notes
Article 24.3(a)	N/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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 24.3(b)	N/A	conformity assessment based on full quality assurance (based on module H) set out in Annex VI.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 24.4	N/A	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].	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 24.5	N/A	Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises (SME) when setting the fees for conformity assessment procedures and reduce those fees proportionately to their specific interests and needs.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 26	Notifying authorities	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 26.1	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 26.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 27	Requirements relating to notifying authorities	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 27.1	N/A	A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 27.2	N/A	A notifying authority shall be organised and shall function so as to safeguard the objectivity and impartiality of its activities.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 27.3	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 27.4	N/A	A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on commercial or competitive basis.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 27.5	N/A	A notifying authority shall safeguard the confidentiality of the information it obtains.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 27.6	N/A	A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 28	Information obligation on notifying authorities	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 28.1	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 28.2	N/A	The Commission shall make that information publicly available.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29	Requirements relating to notified bodies	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.1		For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 12.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.2		A conformity assessment body shall be established under national law and have legal personality.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.3		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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.4	N/A	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, 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, 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.5	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.6	N/A	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 - and - 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.6(a)	N/A	staff with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.6(b)	N/A	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;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.6(c)	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.7	N/A	The personnel responsible for carrying out conformity assessment activities shall have the following:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.7(a)	N/A	sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.7(b)	N/A	satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.7(c)	N/A	appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of its implementing acts;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.7(d)	N/A	the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.8	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.9	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.10	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.11	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 29.12	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 31	Subsidiaries of and subcontracting by notified bodies	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 31.1	N/A	Where a notified body subcontract 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 31.2	N/A	Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 31.3	N/A	Activities may be subcontracted or carried out by a subsidiary only with the agreement of the manufacturer.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 31.4	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 32	Application for notification	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 32.1	N/A	A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control

FDE #	FDE Name	Focal Document Element (FDE) Description	STRM Rationale	STRM Relationship	SCF Control	SCF #	Secure Controls Framework (SCF) Control Description	Strength of Relationship	Notes
Article 32.2	N/A	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 one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 29.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 32.3	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 33	Notification procedure	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 33.1	N/A	Notifying authorities may notify only conformity assessment bodies, which have satisfied the requirements laid down in Article 29.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 33.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 33.3	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 33.4	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 33.5	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 33.6	N/A	The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 34	Identification numbers and lists of notified bodies	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 34.1	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 34.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 35	Changes to notifications	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 35.1	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 35.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 36	Challenge of the competence of notified bodies	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 36.1	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 36.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 36.3	N/A	The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 36.4	N/A	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 identification if necessary.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 37	Operational obligations of notified bodies	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 37.1	N/A	Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedure provided for in Article 24 and Annex VI. 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 37.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 37.3	N/A	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 19 have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 37.4	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 37.6	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 38	Information obligation on notified bodies	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 38.1	N/A	Notified bodies shall inform the notifying authority of the following:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 38.1(a)	N/A	any refusal, restriction, suspension or withdrawal of a certificate;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 38.1(b)	N/A	any circumstances affecting the scope of and conditions for notification;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 38.1(c)	N/A	any request for information which they have received from market surveillance authorities regarding conformity assessment activities;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 38.1(d)	N/A	on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 38.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 40	Coordination of notified bodies	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 40.1	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 40.2	N/A	Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 41	Market surveillance and control of products with digital elements in the Union market	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 41.1	N/A	Regulation (EU) 2019/1020 shall apply to the products with digital elements within the scope of this Regulation.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 41.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 41.3	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 41.4	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 41.5	N/A	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 5 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 41.6	N/A	Member States shall ensure that the designated market surveillance authorities are provided with adequate financial and human resources to fulfil their tasks under this Regulation.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 41.7	N/A	The Commission shall facilitate the exchange of experience between designated market surveillance authorities.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 41.8	N/A	Market surveillance authorities may provide guidance and advice to economic operators on the implementation of this Regulation, with the support of the Commission.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 41.9	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control

FDE #	FDE Name	Focal Document Element (FDE) Description	STRM Rationale	STRM Relationship	SCF Control	SCF #	Secure Controls Framework (SCF) Control Description	Strength of Relationship	Notes
Article 41.10	N/A	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 findings relevant for the fulfilment of their tasks in relation to the implementation of this Regulation.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 41.11	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
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 required to assess the design, development, production and vulnerability handling of such products, including related internal documentation of the respective economic operator.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 43	Procedure at national level concerning products with digital elements presenting a significant cybersecurity risk	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 43.1	N/A	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 operator to take all appropriate corrective actions to bring the product 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 it may prescribe. The market surveillance authority shall inform the market surveillance authority of the other Member States of the measures taken. 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 43.2	N/A	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 operator to take.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 43.3	N/A	The manufacturer shall ensure that all 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 43.4	N/A	Where the manufacturer 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 being made available on its national market, to withdraw it from that market or to recall it. That authority shall inform the Commission and the other Member States, without delay, of those measures.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 43.5	N/A	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 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 operator. In particular, the market surveillance authority shall indicate whether the non-compliance is due to one or more of the following:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 43.5(a)	N/A	a failure of the product or of the processes put in place by the manufacturer to meet the essential requirements set out in Annex I;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 43.5(b)	N/A	shortcomings in the harmonised standards, cybersecurity certification schemes, or common specifications, referred to in Article 18;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 43.6	N/A	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 concerned, and, in the event of disagreement with the notified national measure, of their objections.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 43.7	N/A	Where, within three months of receipt of the information 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 operator concerned in accordance with Article 18 of Regulation (EU) 2019/1020.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 43.8	N/A	The market surveillance authorities of all Member States shall ensure that appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of the product from their market, without delay.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 44	Union safeguard procedure	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 44.1	N/A	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, 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 decision to the Member State concerned.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 44.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 44.3	N/A	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 10 of Regulation (EU) No 1025/2012.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 44.4	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 44.5	N/A	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 19, the Commission shall consider whether to amend or repeal the implementing act referred to in Article 19 setting out those common specifications.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 45	Procedure at EU level concerning products with digital elements presenting a significant cybersecurity risk	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 45.1	N/A	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 may request the relevant market surveillance authorities to carry out an evaluation of compliance and follow the procedures referred to in Article 43.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 45.2	N/A	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 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 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 45.3	N/A	Based on ENISA's evaluation, 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 45.4	N/A	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 from the market, or recalling, 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).	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 45.5	N/A	The Commission shall immediately communicate the decision referred to in paragraph 4 to the relevant economic operator or operators. Member States shall implement the acts referred to in paragraph 4 without delay and shall inform the Commission accordingly.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 45.6	N/A	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 is not brought into compliance with this Regulation.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 46	Compliant products with digital elements which present a significant cybersecurity risk	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control

FDE #	FDE Name	Focal Document Element (FDE) Description	STRM Rationale	STRM Relationship	SCF Control	SCF #	Security Controls Framework (SCF) Control Description	Strength of Relationship	Notes
Article 46.1	N/A	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 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 46.2	N/A	The manufacturer or other relevant 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 46.3	N/A	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 risk involved and the nature and duration of the national measures taken.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 46.4	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 46.5	N/A	The Commission shall address its decision to the Member States.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 46.6	N/A	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 the relevant market surveillance authority or authorities to carry out an evaluation of compliance and follow the procedures referred to in Article 43 and paragraphs 1, 2 and 3 of this Article.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 46.7	N/A	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 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 carry out an evaluation of the risks presented by that product and shall inform the relevant market surveillance authorities accordingly. The relevant economic operators shall cooperate as necessary with ENISA.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 46.8	N/A	Based on ENISA's 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 operator or operators.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 46.9	N/A	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 from the market, or recalling, 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).	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 46.10	N/A	The Commission shall immediately communicate the decision referred to in the paragraph 9 to the relevant operator or operators. Member States shall implement such acts without delay and shall inform the Commission accordingly.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 46.11	N/A	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 continues to present the risks referred to in paragraph 1.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 47	Formal non-compliance	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 47.1	N/A	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:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 47.1(a)	N/A	the conformity marking has been affixed in violation of Articles 21 and 22;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 47.1(b)	N/A	the conformity marking has not been affixed;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 47.1(c)	N/A	the EU declaration of conformity has not been drawn up;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 47.1(d)	N/A	the EU declaration of conformity has not been drawn up correctly;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 47.1(e)	N/A	the identification number of the notified body, which is involved in the conformity assessment procedure, where applicable, has not been affixed;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 47.1(f)	N/A	the technical documentation is either not available or not complete.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 47.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 48	Joint activities of market surveillance authorities	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 48.1	N/A	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 or made available on the market, in particular products that are often found to present cybersecurity risks.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 48.2	N/A	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 falling in the scope of this Regulation with the requirements laid down by the latter.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 48.3	N/A	The market surveillance authorities and 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 48.4	N/A	A market surveillance authority may use any information resulting from the activities carried out as part of any investigation that it undertakes.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 48.5	N/A	The market surveillance authority concerned and the Commission, where applicable, shall make the agreement on joint activities, including the names of the parties involved, available to the public.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 49	Sweeps	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 49.1	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 49.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 49.3	N/A	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 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 49.4	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 49.5	N/A	Market surveillance authorities may invite Commission officials, and other accompanying persons authorised by the Commission, to participate in sweeps.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 50	Exercise of the delegation	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 50.1	N/A	The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 50.2	N/A	The power to adopt delegated acts referred to in Article 2(4), Article 6(2), Article 6(3), Article 6(5), Article 20(5) and Article 23(5) shall be conferred on the Commission.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 50.3	N/A	The delegation of power referred to in Article 2(4), Article 6(2), Article 6(3), Article 6(5), 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 50.4	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 50.5	N/A	As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 50.6	N/A	A delegated act adopted pursuant to Article 2(4), Article 6(2), Article 6(3), Article 6(5), 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 do not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 51	Committee procedure	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 51.1	N/A	The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 51.2	N/A	Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 51.3	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 52	Confidentiality	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 52.1	N/A	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:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control

FDE #	FDE Name	Focal Document Element (FDE) Description	STRM Rationale	STRM Relationship	SCF Control	SCF #	Secure Controls Framework (SCF) Control Description	Strength of Relationship	Notes
Article 52.1(a)	N/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;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 52.1(b)	N/A	the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 52.1(c)	N/A	public and national security interests;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 52.1(d)	N/A	integrity of criminal or administrative proceedings.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 52.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 52.3	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 52.4	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53	Penalties	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.1	N/A	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. The penalties provided for shall be effective, proportionate and dissuasive.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.3	N/A	The non-compliance with the essential cybersecurity requirements laid down in Annex 1 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 its total worldwide annual turnover for the preceding financial year, whichever is higher.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.4	N/A	The non-compliance with any other obligations 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.5	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.6	N/A	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:	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.6(a)	N/A	the nature, gravity and duration of the infringement and of its consequences;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.6(b)	N/A	whether administrative fines have been already applied by other market surveillance authorities to the same operator for a similar infringement;	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.6(c)	N/A	the size and market share of the operator committing the infringement.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.7	N/A	Market surveillance authorities that apply administrative fines shall share this 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.8	N/A	Each Member State shall lay down rules on whether and to what extent administrative fines may be imposed on public authorities and bodies established in that Member State.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.9	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 53.10	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 54	Amendment to Regulation (EU) 2019/1020	In Annex 1 to Regulation (EU) 2019/1020 the following point is added: "71. [Regulation XXX] (Cyber Resilience Act)"	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 55	Transitional provisions	N/A	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 55.1	N/A	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 142 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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 55.2	N/A	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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
Article 55.3	N/A	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].	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
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.	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control
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 months after the date of entry into force of this Regulation]. However Article 11 shall apply from [12 months after the date of entry into force of this Regulation].	Functional	No Relationship	N/A	N/A	N/A	0	No applicable SCF control