

EUROPEAN COMMISSION

> Brussels, XXX [...](2025) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

on the technical description of the categories of important and critical products with digital elements pursuant to Regulation (EU) 2024/2847 of the European Parliament and of the Council

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act)¹, and in particular Article 7(4) thereof,

Whereas:

- (1) Regulation (EU) 2024/2847 lays down rules on the cybersecurity of products with digital elements. In particular, Article 7(2) of that Regulation sets out categories of important products with digital elements that are subject to conformity assessment procedures that are stricter than those applicable to other products with digital elements. Article 8(2) of Regulation (EU) 2024/2847 sets out categories of critical products with digital elements for which manufacturers could be required to obtain a European cybersecurity certificate under a European cybersecurity certification scheme pursuant to Regulation (EU) 2019/881 of the European Parliament and of the Council² or which would be subject to strict conformity assessment procedures.
- (2) Pursuant to Article 7(1) and Article 8(1) of Regulation (EU) 2024/2847, the core functionality of a product with digital elements determines whether that product with digital elements fits into the technical description of a category of important or critical products with digital elements and therefore the applicable conformity assessment procedures. A product's core functionality refers to its fundamental features and capabilities that fulfil the primary purpose for which the product with digital elements has been made available on the market and without which the product would not be able to meet its intended purpose or reasonably foreseeable use.
- (3) When developing a product with digital elements, and in order to achieve their desired set of functionalities, manufacturers typically integrate into their own products with digital elements other products with digital elements that can meet the technical description of a category of important or critical products. Pursuant to Regulation (EU) 2024/2847, the integration of a product with digital elements which has the core

¹ OJ L, 20.11.2024, ELI: <u>http://data.europa.eu/eli/reg/2024/2847/oj</u>

² Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15, ELI: <u>http://data.europa.eu/eli/reg/2019/881/oj</u>).

functionality of a product category set out in Annex III and Annex IV to Regulation (EU) 2024/2847 does not in itself render the product in which it is integrated subject to the conformity assessment procedures applicable to those product categories.

- (4) The fact that a product with digital elements performs functions other than or additional to those detailed in the technical descriptions set out in the Annexes does not in itself mean that the product with digital elements does not have the core functionality of a product category set out in the Annexes. For example, products with digital elements that have the core functionality of "operating systems" often include software that performs ancillary functions not included in the technical description of that product category, such as calculators or simple graphics editors. This, however, does not in itself mean that such products with digital elements do not meet the technical description of "operating systems". On the other hand, a security orchestration, automation and response (SOAR) software often has the ability to perform the functions of products with digital elements in the category of "security information and event management (SIEM) systems", i.e. gather data, analyse it and present it as actionable information for security purposes. However, as its core functionality is to integrate separate security tools, automate low-level tasks and orchestrate security incident responses, SOAR software are generally not to be considered to meet the technical description of "security information and event management (SIEM) systems".
- (5) Pursuant to Article 13(2) and (3) of Regulation (EU) 2024/2847, manufacturers of products with digital elements are to implement the essential cybersecurity requirements set out in Part I of Annex I to Regulation (EU) 2024/2847 in a way that is proportionate to the risks of the product with digital elements, based on the intended purpose and reasonably foreseeable use as well as the conditions of use of the product with digital elements, taking into account the length of time the product is expected to be in use. In accordance with Article 13(2) and (3) of that Regulation, and irrespective of whether the product with digital elements is considered to be an important or critical product with digital elements, manufacturers are to carry out a comprehensive cybersecurity risk assessment and indicate how the essential cybersecurity requirements are implemented as informed by the risk assessment, including their testing and assurance. Where the core functionality of their product with digital elements fits the technical description of an important or critical product with digital elements, manufacturers are to demonstrate conformity following the specific conformity assessment procedures established by Article 32(2), (3) and (4) of Regulation (EU) 2024/2847.
- (6) This Regulation includes examples of products with digital elements whose core functionality fits into the technical description of certain important or critical products with digital elements. Such examples are provided for illustrative purposes only and are not an exhaustive list.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 62(1) of Regulation (EU) 2024/2847,

HAS ADOPTED THIS REGULATION:

Article 1

- 1. The technical description of the categories of products with digital elements under classes I and II listed in Annex III of Regulation (EU) 2024/2847 shall be as set out in Annex I to this Regulation.
- 2. The technical description of the categories of products with digital elements listed in Annex IV of Regulation (EU) 2024/2847 shall be as set out in the Annex II to this Regulation.

Article 2

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

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

Done at Brussels,

For the Commission The President Ursula von der Leyen