



Brussels, XXX
[...] (2023) XXX draft

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

of XXX

amending Implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 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.

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

of **XXX**

amending Implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC¹, and in particular Article 1(2), in conjunction with Article 9(1), thereof,

Whereas:

- (1) Article 2(1) and (2) of Commission Implementing Regulation (EU) 2022/2346² set out transitional provisions for products for which clinical investigations are performed or for which a notified body has to be involved in the conformity assessment. Article 2(3) of that Implementing Regulation also sets out specific transitional provisions for products covered by a certificate issued by a notified body in accordance with Council Directive 93/42/EEC³.
- (2) Regulation (EU) 2023/607 of the European Parliament and of the Council⁴ extended the transitional period provided for in Regulation (EU) 2017/745 for certain medical devices, including those which are covered by a certificate issued by a notified body in accordance with Directive 93/42/EEC that is valid, until 31 December 2027 or 31 December 2028, depending on the risk class of the device.
- (3) To ensure consistency and provide legal certainty for economic operators, the transitional provisions set out in Implementing Regulation (EU) 2022/2346 for products covered by a certificate issued by a notified body in accordance with Directive 93/42/EEC should be aligned with those set out in Regulation (EU) 2017/745, as amended by Regulation (EU) 2023/607.
- (4) Products covered by a certificate issued by a notified body in accordance with Directive 93/42/EEC benefit from a specific transitional provision laid down in Implementing Regulation (EU) 2022/2346. The provision has been applicable since 22

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¹ OJ L 117, 5.5.2017, p. 1.

² Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (OJ L 311, 2.12.2022, p. 60).

³ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

⁴ Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices (OJ L 80, 20.3.2023, p. 24).

December 2022 and allows those products to be placed on the market or put into service subject to certain conditions, even if the certificate has expired. To the extent that such products do not benefit from the extended transitional provisions provided for in Regulation (EU) 2017/745, as amended by Regulation (EU) 2023/607, the possibility to continue to place them on the market or put them into service even if the certificate issued by a notified body in accordance with Directive 93/42/EEC has expired, should be provided as a specific transitional provision in this Regulation. To ensure consistency, applicable conditions set out in Article 120 of Regulation (EU) 2017/745, as amended by Regulation (EU) 2023/607, should be met.

- (5) In order to reduce as much as possible the overlap with conformity assessments of medical devices covered by a certificate issued by a notified body in accordance with Directive 93/42/EEC and thereby reduce the burden on notified bodies and the risk of shortages of devices, the transitional provisions in Implementing Regulation (EU) 2022/2346 for products for which clinical investigations are performed or for which a notified body has to be involved in the conformity assessment procedure should be extended by 18 and 30 months, respectively.
- (6) The transitional provisions in Implementing Regulation (EU) 2022/2346 for products for which clinical investigations are performed or for which a notified body has to be involved in the conformity assessment procedure apply from 22 June 2023. In order to ensure that those products can benefit directly from the extended transitional provisions, the relevant provisions of this Regulation should apply from the same date. Products covered by a certificate issued by a notified body in accordance with Directive 93/42/EEC have benefitted from the transitional provisions set out in Implementing Regulation (EU) 2022/2346 from 22 December 2022. In order to ensure that those products can smoothly benefit from the extended transitional provisions and considering that the specific conditions set out in this Regulation ensure continuity with those previously applicable, the relevant provision of this Regulation should also apply from 22 June 2023. Consequently, the former provision setting out the applicability from 22 December 2022 should be deleted from Implementing Regulation (EU) 2022/2346 from the date of application of the amended provision set out in this Regulation.
- (7) To ensure that economic operators can rapidly access and implement the extended transitional provisions established by this Regulation, it should become applicable from the day of its publication in the *Official Journal of the European Union*.
- (8) Implementing Regulation (EU) 2022/2346 should therefore be amended accordingly.
- (9) The Medical Device Coordination Group has been consulted.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2022/2346 is amended as follows:

- (1) Article 2 is amended as follows:
 - (a) paragraph 1 is amended as follows:

- (i) in the first subparagraph, the date ‘22 June 2028’ is replaced by ‘31 December 2029’;
 - (ii) in the third subparagraph, the date ‘22 June 2026’ is replaced by ‘31 December 2027’;
 - (iii) the fourth subparagraph is replaced by the following:

‘By way of derogation from the first subparagraph, from 1 January 2028 until 31 December 2029, a product that meets the conditions laid down in that subparagraph may only be placed on the market or put into service, if a written agreement for the performance of the conformity assessment has been signed by the notified body and the manufacturer in accordance with Section 4.3, second subparagraph, of Annex VII to Regulation (EU) 2017/745.’;
- (b) paragraph 2 is amended as follows:
- (i) in the first subparagraph, the date ‘22 June 2025’ is replaced by ‘31 December 2028’;
 - (ii) the second subparagraph is replaced by the following:

‘By way of derogation from the first subparagraph, from 1 January 2027 until 31 December 2028, a product that meets the conditions laid down in that subparagraph may only be placed on the market or put into service, if a written agreement for the performance of the conformity assessment has been signed by the notified body and the manufacturer in accordance with Section 4.3, second subparagraph, of Annex VII to Regulation (EU) 2017/745.’;
- (c) paragraph 3 is replaced by the following:
- ‘3. A product which was covered by a certificate issued by a notified body in accordance with Directive 93/42/EEC that expired after 26 May 2021 and before 20 March 2023, and for which the conditions laid down in Article 120(2), second subparagraph, point (a) or (b), of Regulation (EU) 2017/745 are not met, may be placed on the market or put into service until the dates laid down in Article 120(3a) of Regulation (EU) 2017/745, also after the expiry of the certificate, provided that the conditions set out in Article 120 (3c), (3d) and (3e), of Regulation (EU) 2017/745 are met.’;
- (2) in Article 3(2), the second sentence is deleted.

Article 2

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

It shall apply from 22 June 2023.

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

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