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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4), point (c), thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Regulations (EU) 2017/745 ([3]) and (EU) 2017/746 ([4]) of the European Parliament and of the Council establish a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices and *in vitro* diagnostic medical devices, taking as a base a high level of protection of health for patients and users. At the same time, Regulations (EU) 2017/745 and (EU) 2017/746 set high standards of quality and safety for medical devices and *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, both Regulations significantly reinforce key elements of the previous regulatory framework set out in Council Directives 90/385/EEC ([5]) and 93/42/EEC ([6]) and Directive 98/79/EC of the European Parliament and of the Council ([7]), such as the supervision of notified bodies, risk classification, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and introduce provisions ensuring transparency and traceability in respect of medical devices and *in vitro* diagnostic medical devices.

(2) Due to the impact of the COVID-19 pandemic, the date of application of Regulation (EU) 2017/745 was postponed by one year to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council ([8]), while 26 May 2024 was maintained as the end date of the transitional period by which certain devices that continue to comply with Directive 90/385/EEC or Directive 93/42/EEC can lawfully be placed on the market or put into service.

([1]) Opinion of 24 January 2023 (not yet published in the Official Journal).

([2]) Position of the European Parliament of 16 February 2023 (not yet published in the Official Journal) and decision of the Council of 7 March 2023.

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

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

([5]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

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

([7]) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

([8]) Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130, 24.4.2020, p. 18).

(3) Also due to the impact of the COVID-19 pandemic, the transitional period provided for in Regulation (EU) 2017/746 was already extended by Regulation (EU) 2022/112 of the European Parliament and of the Council ([9]).

(4) Despite the steady increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/745, the overall capacity of notified bodies is still not sufficient to ensure the conformity assessment of the large number of devices covered by certificates issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC before 26 May 2024. It appears that a large number of manufacturers, especially small and medium-sized enterprises, are not sufficiently prepared to demonstrate compliance with the requirements of Regulation (EU) 2017/745, in particular when the complexity of those new requirements is taken into account. Therefore, it is very likely that many devices that can lawfully be placed on the market in accordance with the transitional provisions provided for in Regulation (EU) 2017/745 will not be certified in accordance with that Regulation before the end of the transitional period, which leads to the risk of shortages of medical devices in the Union.

(5) In light of reports from healthcare professionals about the imminent risk of shortages of devices, it is necessary, as a matter of urgency, to extend the validity of certificates issued in accordance with Directives 90/385/EEC and 93/42/EEC and to extend the transitional period during which devices that are in conformity with those Directives can lawfully be placed on the market. The extension should be of sufficient duration to give notified bodies the time needed to carry out the conformity assessments required of them. The extension aims to ensure a high level of public health protection, including patient safety and an avoidance of shortages of medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements.

(6) The extension should be subject to certain conditions to ensure that only devices that are safe and for which the manufacturers have taken certain steps to transition towards compliance with Regulation (EU) 2017/745 will benefit from the additional time.

(7) To ensure a progressive transition to Regulation (EU) 2017/745, the appropriate surveillance regarding devices benefiting from the transitional period should eventually be transferred from the notified body that issued the certificate in accordance with Directive 90/385/EEC or Directive 93/42/EEC to a notified body designated under Regulation (EU) 2017/745. For reasons of legal certainty, the notified body designated under Regulation (EU) 2017/745 should not be responsible for conformity assessment and surveillance activities carried out by the notified body that issued the certificate.

(8) As regards the period needed to allow manufacturers and notified bodies to carry out the conformity assessment in accordance with Regulation (EU) 2017/745 of medical devices that are covered by a certificate or a declaration of conformity that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC, a balance should be struck between the limited available capacity of notified bodies and ensuring a high level of patient safety and public health protection. Therefore, the length of the transitional period should depend on the risk class of the medical devices concerned, so that the period is shorter for devices belonging to a higher risk class and longer for devices belonging to a lower risk class.

(9) Contrary to Directives 90/385/EEC and 93/42/EEC, Regulation (EU) 2017/745 requires the involvement of a notified body in the conformity assessment of class III custom-made implantable devices. Due to insufficient notified body capacity and the fact that manufacturers of custom-made devices are often small or medium-sized enterprises which lack access to a notified body under Directives 90/385/EEC and 93/42/EEC, a transitional period should be provided for, during which class III custom-made implantable devices can lawfully be placed on the market or put into service without a certificate issued by a notified body.

([9]) Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of conditions for in-house devices (OJ L 19, 28.1.2022, p. 3).

(10) Article 120(4) of Regulation (EU) 2017/745 and Article 110(4) of Regulation (EU) 2017/746 prohibit the further making available on the market or putting into service of devices which are placed on the market by the end of the applicable transitional period and which are still in the supply chain one year after the end of that transitional period. To prevent the unnecessary disposal of safe medical devices and *in vitro* diagnostic medical devices that are still in the supply chain, thus adding to the imminent risk of shortages of such devices, such further making available on the market or putting into service of such devices should be unlimited in time.

(11) Regulations (EU) 2017/745 and (EU) 2017/746 should therefore be amended accordingly.

(12) Since the objectives of this Regulation, namely to address risks of shortages of medical devices and *in vitro* diagnostic medical devices in the Union, cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union ('TEU'). In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(13) This Regulation is being adopted in view of the exceptional circumstances arising from an imminent risk of shortages of medical devices and the associated risk of a public health crisis. In order to attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure availability of devices whose certificates have already expired or are due to expire before 26 May 2024, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, this Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union*. For the same reasons, it is also considered to be appropriate to invoke the exception to the eight-week period provided for in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the TEU, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2017/745

Regulation (EU) 2017/745 is amended as follows:

(1) Article 120 is amended as follows:

(a) in paragraph 2, the second subparagraph is replaced by the following:

'Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date set out in paragraph 3a of this Article applicable for the relevant risk class of the devices. Certificates issued by notified bodies in accordance with those Directives from 25 May 2017 that were still valid on 26 May 2021 and that have expired before 20 March 2023 shall be considered to be valid until the dates set out in paragraph 3a of this Article only if one of the following conditions is fulfilled:

(a) before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device;

(b) a competent authority of a Member State has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) of this Regulation or has required the manufacturer, in accordance with Article 97(1) of this Regulation, to carry out the applicable conformity assessment procedure.';

(b) paragraph 3 is replaced by the following:

'3. By way of derogation from Article 5 and provided the conditions set out in paragraph 3c of this Article are met, devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates set out in those paragraphs.

3a. Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:

(a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;

(b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

3b. Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until 31 December 2028.

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

(b) there are no significant changes in the design and intended purpose;

(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);

(e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

3d. By way of derogation from paragraph 3 of this Article, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to devices referred to in paragraphs 3a and 3b of this Article in place of the corresponding requirements in Directives 90/385/EEC and 93/42/EEC.

3e. Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in paragraph 3a of this Article shall continue to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices it has certified, unless the manufacturer has agreed with a notified body designated in accordance with Article 42 that the latter shall carry out such surveillance.

No later than 26 September 2024, the notified body that has signed the written agreement referred to in paragraph 3c, point (e), of this Article shall be responsible for the surveillance in respect of the devices covered by the written agreement. Where the written agreement covers a device intended to substitute a device which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC, the surveillance shall be conducted in respect of the device that is being substituted.

The arrangements for the transfer of the surveillance from the notified body that issued the certificate to the notified body designated in accordance with Article 42 shall be clearly defined in an agreement between the manufacturer and the notified body designated in accordance with Article 42 and, where practicable, the notified body that issued the certificate. The notified body designated in accordance with Article 42 shall not be responsible for conformity assessment activities carried out by the notified body that issued the certificate.

3f. By way of derogation from Article 5, class III custom-made implantable devices may be placed on the market or put into service until 26 May 2026 without a certificate issued by a notified body in accordance with the conformity assessment procedure referred to in Article 52(8), second subparagraph, provided that no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.';

(c) paragraph 4 is replaced by the following:

'4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices lawfully placed on the market from 26 May 2021 pursuant to paragraphs 3, 3a, 3b and 3f of this Article, may continue to be made available on the market or put into service.';

(2) Article 122 is amended as follows:

(a) in the first paragraph, the introductory wording is replaced by the following:

'Without prejudice to Article 120(3) to (3e) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and to the obligations of manufacturers as regards the making available of documentation, under Directives 90/385/EEC and 93/42/EEC, those Directives are repealed with effect from 26 May 2021, with the exception of:';

(b) the second paragraph is replaced by the following:

'As regards the devices referred to in Article 120(3) to (3e) and (4) of this Regulation, the Directives referred to in the first paragraph of this Article shall continue to apply to the extent necessary for the application of those paragraphs.';

(3) in Article 123(3), point (d), the 24th indent is replaced by the following:

'— Article 120(3d).'.

Article 2

Amendments to Regulation (EU) 2017/746

Regulation (EU) 2017/746 is amended as follows:

(1) in Article 110, paragraph 4 is replaced by the following:

'4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022, and devices lawfully placed on the market from 26 May 2022 pursuant to paragraph 3 of this Article may continue to be made available on the market or put into service.';

(2) in Article 112, the second paragraph is replaced by the following:

'As regards the devices referred to in Article 110(3) and (4) of this Regulation, Directive 98/79/EC shall continue to apply to the extent necessary for the application of those paragraphs.'.

Article 3

Entry into force

This Regulation shall enter into force on the day 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 Strasbourg, 15 March 2023.

For the European Parliament	*For the Council*
The President	*The President*
R. METSOLA	J. ROSWALL