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 (Text with EEA relevance)

CHAPTER X

FINAL PROVISIONS

Article 114

Committee procedure

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

2 Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

4 Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or 5 thereof, as appropriate, shall apply.

Article 115

Exercise of the delegation

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Articles 1(5), 3, 10(4), 18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) shall be conferred on the Commission for a period of five years from 25 May 2017. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3 The delegation of power referred to in Articles 1(5), 3, 10(4), 18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6 A delegated act adopted pursuant to Articles 1(5), 3, 10(4), 18(3), 19(4), 27(10), 44(11), 52(5), 56(6), 61(8), 70(8) and 106(15) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Article 116

Separate delegated acts for different delegated powers

The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation.

Article 117

Amendment to Directive 2001/83/EC

In Annex I to Directive 2001/83/EC, point 12 of Section 3.2. is replaced by the following:

(12) Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council[(1)], a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question..

Article 118

Amendment to Regulation (EC) No 178/2002

In the third paragraph of Article 2 of Regulation (EC) No 178/2002, the following point is added:

(i) medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council[(2)]..

Article 119

Amendment to Regulation (EC) No 1223/2009

In Article 2 of Regulation (EC) No 1223/2009, the following paragraph is added:

4. The Commission may, at the request of a Member State or on its own initiative, adopt the necessary measures to determine whether or not a specific product or group of products falls within the definition 'cosmetic product'. Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 32(2)..

Article 120

Transitional provisions

1 From 26 May 2020, any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void.

2 Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 to Directive 90/385/EEC or Annex IV to Directive 93/42/EEC which shall become void at the latest on 27 May 2022.

Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.

[[X1]3 By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2020 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, or which has 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 26 May 2024, provided that from 26 May 2020 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.**]**

Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified.

4 Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2020, and devices placed **[**[X1]on the market from 26 May 2020 pursuant to paragraph 3 of this Article, may continue to be made available on the market or put into service until 26 May 2025.**]**

5 By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market prior to 26 May 2020.

6 By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated **[**X2and notified prior to 26 May 2020. Notified bodies**]** which are designated and notified in accordance with this Regulation may carry out the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation prior to 26 May 2020.

7 As regards devices subject to the consultation procedure laid down in Article 54, paragraph 5 of this Article shall apply provided that the necessary appointments to the MDCG and expert panels have been made.

[X1 8 By way of derogation from Article 10a, point (a) of Article 10b(1) and Article 11(5) of Directive 90/385/EEC and Article 14(1) and (2), points (a) and (b) of Article 14a(1) and Article 16(5) of Directive 93/42/EEC, manufacturers, authorised representatives, importers and notified bodies which, during the period starting on the later of the dates referred to in point (d) of Article 123(3) and ending 18 months later, comply with Articles 29(4), 31(1) and 56(5) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with, respectively, Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC, with, respectively, point (a) of Article 10b(1) of Directive 90/385/EEC or points (a) and (b) of Article 14a(1) of Directive 93/42/EEC and with, respectively, Article 11(5) of Directive 90/385/EEC or Article 16(5) of Directive 93/42/EEC, as specified in Decision 2010/227/EU.**]**

9 Authorisations granted by the competent authorities of the Member States in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC shall keep the validity indicated in the authorisation.

10 **[**X2Devices falling within the scope of this Regulation in accordance with point (g) of Article 1(6) which**]** have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to 26 May 2020 may continue to be placed on the market and put into service in the Member States concerned.

11 Clinical investigations which have started to be conducted in accordance with Article 10 of Directive 90/385/EEC or Article 15 of Directive 93/42/EEC prior to 26 May 2020 may continue to be conducted. As of 26 May 2020, however, the reporting of serious adverse events and device deficiencies shall be carried out in accordance with this Regulation.

12 Until the Commission has designated, pursuant to Article 27(2), issuing entities, GS1, HIBCC and ICCBBA shall be considered to be designated issuing entities.

Editorial Information

X1 Substituted by Corrigendum 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/EEC (Official Journal of the European Union L 117 of 5 May 2017).

X2 Substituted by Corrigendum 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/EEC (Official Journal of the European Union L 117 of 5 May 2017).

Article 121

Evaluation

By 27 May 2027, the Commission shall assess the application of this Regulation and produce an evaluation report on the progress towards achievement of the objectives contained herein including an assessment of the resources required to implement this Regulation. Special attention shall be given to the traceability of medical devices through the storage, pursuant to Article 27, of the UDI by economic operators, health institutions and health professionals.

Article 122

Repeal

Without prejudice to Articles 120(3) 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 2020, with the exception of:

— Articles 8 and 10, points (b) and (c) of Article 10b(1), Article 10b(2) and Article 10b(3) of Directive 90/385/EEC, and the obligations relating to vigilance and clinical investigations provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in point (d) of Article 123(3) of this Regulation;

— **[**[X1]Article 10a, point (a) of Article 10b(1) and Article 11(5) of Directive 90/385/EEC, and the obligations relating to registration of devices and economic operators, and to certificate notifications, provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in point (d) of Article 123(3) of this Regulation;**]**

— Article 10, points (c) and (d) of Article 14a(1), Article 14a(2), Article 14a(3) and Article 15 of Directive 93/42/EEC, and the obligations relating to vigilance and clinical investigations provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in point (d) of Article 123(3) of this Regulation; and

— **[**[X1]Article 14(1) and (2), points (a) and (b) of Article 14a(1) and Article 16(5) of Directive 93/42/EEC, and the obligations relating to registration of devices and economic operators, and to certificate notifications, provided for in the corresponding Annexes, which are repealed with effect from 18 months after the later of the dates referred to in point (d) of Article 123(3) of this Regulation.**]**

As regards the devices referred to in Article 120 (3) and (4) of this Regulation, the Directives referred to in the first paragraph shall continue to apply until 27 May 2025 to the extent necessary for the application of those paragraphs.

Notwithstanding the first paragraph, Regulations (EU) No 207/2012 and (EU) No 722/2012 shall remain in force and continue to apply unless and until repealed by implementing acts adopted by the Commission pursuant to this Regulation.

References to the repealed Directives shall be understood as references to this Regulation and shall be read in accordance with the correlation table laid down in Annex XVII to this Regulation.

Editorial Information

X1 Substituted by Corrigendum 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/EEC (Official Journal of the European Union L 117 of 5 May 2017).

Article 123

Entry into force and date of application

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

2 It shall apply from 26 May 2020.

3 By way of derogation from paragraph 2:

a Articles 35 to 50 shall apply from 26 November 2017. However, from that date until 26 May 2020, the obligations on notified bodies pursuant to Articles 35 to 50 shall apply only to those bodies which submit an application for designation in accordance with Article 38;

b Articles 101 and 103 shall apply from 26 November 2017;

c Article 102 shall apply from 26 May 2018;

d without prejudice to the obligations on the Commission pursuant to Article 34, where, due to circumstances that could not reasonably have been foreseen when drafting the plan referred to in Article 34(1), Eudamed is not fully functional on 26 May 2020, the obligations and requirements that relate to Eudamed shall apply from the date corresponding to six months after the date of publication of the notice referred to in Article 34(3). The provisions referred to in the preceding sentence are:

— Article 29,
— Article 31,
— Article 32,
— Article 33(4),
— the second sentence of Article 40(2),
— Article 42(10),
— Article 43(2),
— the second subparagraph of Article 44(12),
— points (d) and (e) of Article 46(7),
— Article 53(2),
— Article 54(3),
— Article 55(1),
— Articles 70 to 77,
— paragraphs 1 to 13 of Article 78,
— Articles 79 to 82,
— Article 86(2),

— Articles 87 and 88,
— Article 89(5) and (7), and the third subparagraph of Article 89(8),
— Article 90,
— Article 93(4), (7) and (8),
— Article 95(2) and (4),
— the last sentence of Article 97(2),
— Article 99(4),
— the second sentence of the first subparagraph of Article 120(3).

Until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and 93/42/EEC shall continue to apply for the purpose of meeting the obligations laid down in the provisions listed in the first paragraph of this point regarding exchange of information including, and in particular, information regarding vigilance reporting, clinical investigations, registration of devices and economic operators, and certificate notifications.

e Article 29(4) and Article 56(5) shall apply from 18 months after the later of the dates referred to in point (d);

f for implantable devices and for class III devices Article 27(4) shall apply from 26 May 2021. For class IIa and class IIb devices Article 27(4) shall apply from 26 May 2023. For class I devices Article 27(4) shall apply from 26 May 2025;

g for reusable devices that shall bear the UDI carrier on the device itself, Article 27(4) shall apply from two years after the date referred to in point (f) of this paragraph for the respective class of devices in that point;

h The procedure set out in Article 78 shall apply from 26 May 2027, without prejudice to Article 78(14);

i Article 120(12) shall apply from 26 May 2019.

(**1**) 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).'.

(**2**) 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).'.

Status:
Point in time view as at 05/05/2017.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2017/745 of the European Parliament and of the Council, CHAPTER X.