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 (Text with EEA relevance)

CHAPTER X

FINAL PROVISIONS

Article 107

Committee procedure

1 The Commission shall be assisted by the Committee on Medical Devices established by Article 114 of Regulation (EU) 2017/745. 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 108

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 10(4), 17(4), 24(10), 51(6) and 66(8) 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 10(4), 17(4), 24(10), 51(6) and 66(8) 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 10(4), 17(4), 24(10), 51(6) and 66(8) 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 109

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 110

Transitional provisions

1 From 26 May 2022, any publication of a notification in respect of a notified body in accordance with Directive 98/79/EC shall become void.

2 Certificates issued by notified bodies in accordance with Directive 98/79/EC 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 VI to Directive 98/79/EC which shall become void at the latest on 27 May 2024.

Certificates issued by notified bodies in accordance with Directive 98/79/EC from 25 May 2017 shall become void by 27 May 2024.

3 By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 98/79/EC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with that Directive, 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 and replace the corresponding requirements in that Directive.

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 applicable requirements relating to the devices it has certified.

[[X1]4 Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022 and devices placed on the market from 26 May 2022 by virtue of a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into service until 27 May 2025.**]**

5 By way of derogation from Directive 98/79/EC, devices which comply with this Regulation may be placed on the market before 26 May 2022.

6 By way of derogation from Directive 98/79/EC, conformity assessment bodies which comply with this Regulation may be designated and notified prior to 26 May 2022. 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 2022.

7 As regards devices subject to the procedures laid down in Article 48(3) and (4), paragraph 5 of this Article applies provided that the necessary appointments to the MDCG and expert panels and of EU reference laboratories have been made.

[[X2]8 By way of derogation from Article 10, points (a) and (b) of Article 12(1) and Article 15(5) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies which, during the period starting on the later of the dates referred to in point (f) of Article 113(3) and ending 18 months later, comply with Articles 26(3), 28(1) and 51(5) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10, points (a) and (b) of Article 12(1) and Article 15(5) of Directive 98/79/EC as specified in Decision 2010/227/EU.**]**

9 Authorisations granted by the competent authorities of the Member States in accordance with Article 9(12) of Directive 98/79/EC shall keep the validity indicated in the authorisation.

10 Until the Commission has designated, pursuant to Article 24(2), issuing entities, GS1, HIBCC and ICCBBA shall be considered to be designated issuing entities.

Editorial Information

X1 Substituted by Corrigendum to Regulation (EU) 2017/746 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 (Official Journal of the European Union L 117 of 5 May 2017).

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

Article 111

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 devices through the storage, pursuant to Article 24, of the UDI by economic operators, health institutions and health professionals. The evaluation shall also include a review on the functioning of Article 4.

Article 112

Repeal

Without prejudice to Articles 110 (3) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and the

obligations of manufacturers as regards the making available of documentation, under Directive 98/79/EC, that Directive is repealed with effect from 26 May 2022 with the exception of:

(a) Article 11, point (c) of Article 12(1) and Article 12(2) and (3) of Directive 98/79/EC, and the obligations relating to vigilance and performance studies provided for in the corresponding Annexes, which are repealed with effect from the later of the dates referred to in Article 113(2) and point (f) of Article 113(3) of this Regulation; and

(b) **[**[X2]Article 10, points (a) and (b) of Article 12(1) and Article 15(5) of Directive 98/79/EC, and the obligations relating to registration of devices and economic operators, and 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 Article 113(2) and point (f) of Article 113(3) of this Regulation.**]**

As regards the devices referred to in Article 110(3) and (4) of this Regulation, Directive 98/79/EC shall continue to apply until 27 May 2025 to the extent necessary for the application of those paragraphs.

Decision 2010/227/EU adopted in implementation of Directives 90/385/EEC, 93/42/EEC and 98/79/EC shall be repealed with effect from the later of the dates referred to in Article 113(2) and point (f) of Article 113(3) of this Regulation.

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

Editorial Information

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

Article 113

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 2022.

3 By way of derogation from paragraph 2:

[[X2]a Articles 26(3) and 51(5) shall apply from 18 months after the later of the dates referred to in point (f);**]**

b Articles 31 to 46 and Article 96 shall apply from 26 November 2017. However, from that date until 26 May 2022 the obligations on notified bodies pursuant to Articles 31 to 46 shall apply only to those bodies which submit an application for designation in accordance with Article 34;

c Article 97 shall apply from 26 May 2018;

d Article 100 shall apply from 25 November 2020;

e for class D devices, Article 24(4) shall apply from 26 May 2023. For class B and class C devices Article 24(4) shall apply from 26 May 2025. For class A devices Article 24(4) shall apply from 26 May 2027;

f without prejudice to the obligations on the Commission pursuant to Article 34 of Regulation (EU) 2017/745, where, due to circumstances that could not reasonably have been foreseen when drafting the plan referred to in Article 34(1) of that Regulation, Eudamed is not fully functional on 26 May 2022, 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) of that Regulation. The provisions referred to in the preceding sentence are:

— Article 26,
— Article 28,
— Article 29,
— the second sentence of Article 36(2),
— Article 38(10),
— Article 39(2),
— the second subparagraph of Article 40(12),
— points (d) and (e) of Article 42(7),
— Article 49(2),
— Article 50(1),
— Articles 66 to 73,
— paragraphs 1 to 13 of Article 74,
— Articles 75 to 77,
— Article 81(2),
— Articles 82 and 83,
— Article 84(5) and (7) and the third subparagraph of Article 84(8),
— Article 85,
— Article 88(4), (7) and (8),
— Article 90(2) and (4),
— the last sentence of Article 92(2),
— Article 94(4),
— the second sentence of the first subparagraph of Article 110(3).

Until Eudamed is fully functional the corresponding provisions of Directive 98/79/EC 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 performance studies, vigilance reporting, registration of devices and economic operators, and certificate notifications.

[[X1]g the procedure set out in Article 74 shall apply from 26 May 2029 without prejudice to Article 74(14);**]**

h Article 110(10) shall apply from 26 May 2019.

Editorial Information

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

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

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EU) 2017/746 of the European Parliament and of the Council, CHAPTER X.