Article 120: Transitional provisions

1. From 26 May 2021, 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with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date set out in paragraph 3a of this Article applicable for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.

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 and 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 and 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 3aand 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 DDirective 90/385/EEC and 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.

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.'

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 2021.

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 and notified prior to 26 May 2021. 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 2021.

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.

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. Devices 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 2021 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 2021 may continue to be conducted. As of 26 May 2021, 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.

Article 122: Repeal

Without prejudice to Articles 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:

- — 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;
- — Article 9(9) of Directive 90/385/EEC and Article 11(13) of Directive 93/42/EEC, which are repealed with effect from 24 April 2020.
- — 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

- — Article 14(1) and (2) and 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) to (3e) and (4) of this Regulation, the Directives referred to in the first paragraph shall continue to apply 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.

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 2021.

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 2021, 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 2021, 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 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(3d).

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) with regard to reusable devices that are required to bear the UDI carrier on the device itself, Article 27(4) shall apply to:

    - (i) implantable devices and class III devices from 26 May 2023;
    - (ii) class IIa and class IIb devices from 26 May 2025;
    - (iii) class I devices from 26 May 2027;
- (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.
- (j) Article 59 shall apply from 24 April 2020.

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