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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain *in vitro* diagnostic medical devices - Outcome of the European Parliament's first reading (Strasbourg, 22 to 25 April 2024)

I. INTRODUCTION

On 21 February 2024, the Permanent Representatives Committee confirmed that should the European Parliament approve the abovementioned Commission's proposal without amendments, the Council would approve the European Parliament's position.

After the plenary approved the request of the Committee on the Environment, Public Health and Food Safety (ENVI) to proceed according to the Rule 163 (urgent procedure) on 23 April 2024, this Committee tabled the Commission's proposal for a Regulation. No amendments were presented.

II. VOTE

The Parliament adopted its first-reading position on 25 April 2024 by taking over the Commission proposal. This position is contained in its legislative resolution.

The Council should therefore be in a position to approve the European Parliament's position as set out in the Annex hereto, thus bringing to a close the first reading for both Institutions.

The act would then be adopted in the wording which corresponds to the Parliament's position.

P9_TA(2024)0368

Gradual roll-out of Eudamed, information obligation in case of interruption of supply and transitional provisions for certain *in vitro* diagnostic medical devices

European Parliament legislative resolution of 25 April 2024 on the proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain *in vitro* diagnostic medical devices (COM(2024)0043 – C9-0010/2024 – 2024/0021(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2024)0043),

– having regard to Article 294(2) and Article 114 and Article 168(4), point (c), of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0010/2024),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 20 March 2024[1],

– after consulting the Committee of the Regions,

– having regard to the undertaking given by the Council representative by letter of 21 February 2024 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

– having regard to Rules 59 and 163 of its Rules of Procedure,

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

[1] Not yet published in the Official Journal.

P9_TC1-COD(2024)0021

Position of the European Parliament adopted at first reading on 25 April 2024 with a view to the adoption of Regulation (EU) 2024/… of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain *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[2],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[3],

[2] Opinion of 20 March 2024 (not yet published in the Official Journal).
[3] Position of the European Parliament of 25 April 2024.

Whereas:

(1) Regulations (EU) 2017/745[4] and (EU) 2017/746[5] of the European Parliament and of the Council establish a 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[6] and 93/42/EEC[7] and in Directive 98/79/EC of the European Parliament and of the Council[8], such as the supervision of notified bodies, risk classification, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, and require the setting up of the European database on medical devices (Eudamed) to enable transparency and traceability in respect of medical devices and *in vitro* diagnostic medical devices.

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4 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, ELI: http://data.europa.eu/eli/reg/2017/745/oj).

5 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, ELI: http://data.europa.eu/eli/reg/2017/746/oj).

6 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, ELI: http://data.europa.eu/eli/dir/1990/385/oj).

7 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1, ELI: http://data.europa.eu/eli/dir/1993/42/oj).

8 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, ELI: http://data.europa.eu/eli/dir/1998/79/oj).

(2) Regulations (EU) 2017/745 and (EU) 2017/746 require the Commission to set up, maintain and manage Eudamed, which includes seven interconnected electronic systems. The development of four electronic systems has been completed and the completion of two further electronic systems is expected in 2024. However, the development of the electronic system on clinical investigations and performance studies has been significantly delayed due to the technical complexity of the requirements and workflows to be implemented.

(3) Pursuant to Regulations (EU) 2017/745 and (EU) 2017/746, the obligations and requirements that relate to Eudamed are to apply from a certain date once the Commission has verified the full functionality of Eudamed and published a notice to that effect. The delayed development of the final electronic system therefore holds back the mandatory use of the individual electronic systems that are available.

(4) The use of the electronic systems that are completed or that are about to be completed would largely support the effective and efficient implementation of Regulations (EU) 2017/745 and (EU) 2017/746, decreasing the administrative burden for economic operators. A gradual roll-out of the individual electronic systems of Eudamed should therefore be allowed once their functionality has been verified in accordance with the procedure laid down in Regulation (EU) 2017/745.

(5) Having regard to the gradual roll-out of Eudamed's electronic systems and to avoid overlapping periods of registration in national databases and in Eudamed, the dates of application of the obligations and requirements that relate to Eudamed and the dates of application of the corresponding national registration requirements based on Directives 90/385/EEC, 93/42/EEC and 98/79/EC should be aligned.

(6) Due to the delay of the development of the electronic system on clinical investigations and performance studies, the timeline for the application of the coordinated assessment for clinical investigations and performance studies should also be adapted, keeping the approach that Member States should first have the possibility to opt-in before participation in the coordinated assessment becomes mandatory for all Member States.

(7) Despite the increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/746, the overall capacity of notified bodies is still not sufficient to ensure the certification of the large number of *in vitro* diagnostic medical devices which are to undergo conformity assessment involving a notified body under that Regulation.

(8) The number of applications for conformity assessment of *in vitro* diagnostic medical devices submitted by manufacturers and the number of certificates issued by notified bodies to date indicate that the transition towards the regulatory framework established by Regulation (EU) 2017/746 has not progressed in a way that would ensure a smooth transition to the new rules under that framework.

(9) It is very likely that many safe and critical *in vitro* diagnostic medical devices, which are essential for the medical diagnosis and treatment of patients, would not be certified in accordance with Regulation (EU) 2017/746 before the end of the transitional periods. This leads to a risk of shortages, especially of highest-risk (class D) devices, by the end of the current transitional period on 26 May 2025. It is therefore necessary to ensure that there is an uninterrupted market supply of *in vitro* diagnostic medical devices in the Union.

(10) In order to ensure a high level of protection of public health and patient safety, while safeguarding the smooth functioning of the internal market, as well as to provide legal certainty and avoid potential market disruption, it is necessary to extend further the transitional periods laid down in Regulation (EU) 2017/746 for devices covered by certificates issued by notified bodies in accordance with Directive 98/79/EC and for devices which are to undergo conformity assessment involving a notified body for the first time under Regulation (EU) 2017/746. To achieve those objectives, the extended transitional period should concern all device classes so as to guarantee a manageable distribution of workload across notified bodies in time, and to avoid any impediment to the certification process.

(11) The extension should be of sufficient duration to give manufacturers and notified bodies the time necessary to carry out the required conformity assessments. The extension should aim to ensure a high level of public health protection, including patient safety and an avoidance of shortages of *in vitro* diagnostic medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements.

(12) The extension should be subject to certain conditions to ensure that only *in vitro* diagnostic medical devices that are safe and for which the manufacturers have taken certain steps to transition towards compliance with Regulation (EU) 2017/746 are to benefit from the additional transitional period.

(13) To ensure a progressive transition to Regulation (EU) 2017/746, the appropriate surveillance regarding *in vitro* diagnostic medical devices benefiting from the transitional period should be transferred from the notified body that issued the certificate in accordance with Directive 98/79/EC to a notified body designated under Regulation (EU) 2017/746. For reasons of legal certainty, the notified body designated under Regulation (EU) 2017/746 should not be responsible for conformity assessment and surveillance activities carried out by the notified body that issued the certificate.

(14) As regards the periods needed to allow manufacturers and notified bodies to carry out the conformity assessment in accordance with Regulation (EU) 2017/746 of *in vitro* diagnostic medical devices that are covered by a certificate or a declaration of conformity that was issued in accordance with Directive 98/79/EC, 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 *in vitro* diagnostic medical devices concerned, so that the period is shorter for such devices belonging to a higher risk class and longer for devices belonging to a lower risk class.

(15) Having regard to the impact that shortages of certain medical devices and *in vitro* diagnostic medical devices can have on patient safety and public health, a prior notice mechanism should be introduced to enable competent authorities and health institutions, in particular, to take mitigating measures where necessary to ensure patient health and safety. Therefore, where manufacturers anticipate, for any reason, the interruption or discontinuation of supply of medical devices or *in vitro* diagnostic medical devices and it is reasonably foreseeable that such interruption or discontinuation can result in serious harm or a risk of serious harm to patients or public health in one or more Member States, the manufacturer should inform the relevant competent authorities as well as the economic operators to whom they directly supply such devices and, where applicable, the health institutions or healthcare professionals to whom they directly supply such devices, thereof. The risk of serious harm to patients or public health can, for example, be due to the relevance of such devices for ensuring essential healthcare services in one or more Member States, the dependency of patient health and safety on the continuous availability of such devices in one or more Member States, or the absence of suitable alternatives, also in light of the expected length of the interruption, the quantities of devices already made available on the market and available stocks or timelines for procuring alternatives for such devices. The information should be provided by the manufacturer and other economic operators in the downstream supply chain until it reaches the relevant health institutions or healthcare professionals. As the risk of shortages of such devices is particularly relevant during the transition from Directives 90/385/EEC, 93/42/EEC and 98/79/EC to Regulations (EU) 2017/745 and (EU) 2017/746, the prior notice mechanism should also apply to devices placed on the market in accordance with the transitional provisions laid down in Regulations (EU) 2017/745 and (EU) 2017/746.

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

(17) Since the objectives of this Regulation, namely to address risks of shortages of *in vitro* diagnostic medical devices in the Union and to facilitate the timely roll-out of Eudamed, cannot be sufficiently achieved by the Member States but can rather, by reason of its 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.

(18) This Regulation is being adopted in view of the exceptional circumstances arising from an imminent risk of shortages of *in vitro* diagnostic medical devices and the associated risk of a public health crisis, as well as the significant delay in the development of the electronic system on clinical investigations and performance studies of Eudamed. In order to attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure the availability of such devices the certificates of which have already expired or are due to expire before 26 May 2025, 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.

(19) To allow manufacturers and other economic operators time to adapt to the obligation to provide notice of an anticipated interruption or discontinuation of supply of certain devices, it is appropriate to defer the application of the provisions related to such an obligation,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) 2017/745

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

(1) the following article is inserted:

‘Article 10a

Obligations in case of interruption or discontinuation of supply of certain devices

1. Where a manufacturer anticipates an interruption or a discontinuation of the supply of a device, other than a custom-made device, and where it is reasonably foreseeable that such interruption or discontinuation could result in serious harm or a risk of serious harm to patients or public health in one or more Member States, the manufacturer shall inform the competent authority of the Member State where it or its authorised representative is established, as well as the economic operators, health institutions and healthcare professionals to whom it directly supplies the device, of the anticipated interruption or discontinuation.

The information referred to in the first subparagraph shall, other than in exceptional circumstances, be provided at least 6 months before the anticipated interruption or discontinuation. The manufacturer shall specify the reasons for the interruption or discontinuation in the information provided to the competent authority.

2. The competent authority that has received the information referred to in paragraph 1 shall, without undue delay, inform the competent authorities of the other Member States and the Commission of the anticipated interruption or discontinuation.

3. The economic operators who have received the information from the manufacturer in accordance with paragraph 1 or from another economic operator in the supply chain shall, without undue delay, inform any other economic operators, health institutions and healthcare professionals to whom they directly supply the device, of the anticipated interruption or discontinuation.’

(2) Article 34 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The Commission shall, in collaboration with the MDCG, draw up the functional specifications for Eudamed. The Commission shall draw up a plan for the implementation of those specifications by 26 May 2018.’;

(b) paragraph 2 is replaced by the following:

‘2. The Commission shall inform the MDCG when, on the basis of independent audit reports, it has verified that one or more of the electronic systems referred to in Article 33(2) are functional and meet the functional specifications drawn up pursuant to paragraph 1 of this Article.’;

(3) in Article 78, paragraph 14 is replaced by the following:

‘14. All Member States shall be required to apply the procedure set out in this Article from the date corresponding to 5 years from the date of publication of the notice referred to in Article 34(3), informing that the electronic system referred to in Article 33(2), point (e), is functional and meets the functional specifications drawn up pursuant to Article 34(1).

Before the date set out in the first subparagraph of this paragraph and at the earliest 6 months from the date of publication of the notice referred to in that subparagraph, the procedure set out in this Article shall be applied only by those Member States in which the clinical investigation is to be conducted which have agreed to apply it.’;

(4) Article 120 is amended as follows:

(a) paragraph 8 is deleted;

(b) the following paragraph is added:

’13. Article 10a shall also apply to devices referred to in paragraphs 3a and 3b of this Article.’;

(5) in Article 122, first paragraph, the first to fourth indents are replaced by the following:

‘– Articles 8 and 10, Article 10b(1), points (b) and (c), and Article 10b(2) and (3) of Directive 90/385/EEC, Article 10, Article 14a(1), points (c) and (d), Article 14a(2) and (3) and Article 15 of Directive 93/42/EEC, and the obligations relating to vigilance and clinical investigations provided for in the corresponding Annexes to those Directives, which are repealed, as applicable, with effect from the date referred to in Article 123(3), point (d), of this Regulation in respect of the application of the obligations and requirements that relate to the electronic systems referred to in Article 33(2), points (e) and (f), respectively, of this Regulation;

– Article 10a, Article 10b(1), point (a), and Article 11(5) of Directive 90/385/EEC, Article 14(1) and (2), Article 14a(1), points (a) and (b), 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 to those Directives, which are repealed, as applicable, with effect from the date referred to in Article 123(3), point (d), of this Regulation in respect of the application of the obligations and requirements that relate to the electronic systems referred to in Article 33(2), points (a) to (d), respectively, of this Regulation;’;

(6) Article 123(3) is amended as follows:

(a) point (d) is amended as follows:

(i) the first subparagraph is amended as follows:

(1) the introductory wording is replaced by the following:

‘without prejudice to the obligations of the Commission pursuant to Article 34, the obligations and requirements that relate to any of the electronic systems referred to in Article 33(2) shall apply from the date corresponding to 6 months from the date of publication of the notice referred to in Article 34(3), informing that the relevant electronic system is functional and meets the functional specifications drawn up pursuant to Article 34(1). The provisions referred to in the preceding sentence are:’;

(2) the following indent is inserted after the twelfth indent:

‘– Article 56(5),’;

(3) the fourteenth indent is replaced by the following:

'– Article 78(1) to (13), without prejudice to Article 78(14),';

(ii) the second subparagraph is replaced by the following:

'Until the date of application of the provisions referred to in the first subparagraph of this point, the corresponding provisions of Directives 90/385/EEC and 93/42/EEC regarding information on vigilance reporting, clinical investigations, registration of devices and economic operators, and certificate notifications shall continue to apply;';

(b) point (e) is replaced by the following:

'(e) no later than 12 months from the date of publication of the notice referred to in Article 34(3) in respect of the electronic system referred to in Article 33(2), points (a) and (b), manufacturers shall ensure that the information to be entered in Eudamed in accordance with Article 29 is entered in that electronic system, including regarding the following devices, provided that those devices are also placed on the market from 6 months from the date of publication of that notice:

(i) devices, other than custom-made devices, for which the manufacturer has undertaken a conformity assessment in accordance with Article 52;

(ii) devices, other than custom-made devices, placed on the market pursuant to Article 120(3), (3a) or (3b), unless the device, for which the manufacturer has undertaken a conformity assessment in accordance with Article 52, is already registered in Eudamed;';

(c) the following points are inserted:

‘(ea) no later than 18 months from the date of publication of the notice referred to in Article 34(3) in respect of the electronic system referred to in Article 33(2), point (d), notified bodies shall ensure that the information to be entered in Eudamed in accordance with Article 56(5) is entered in that electronic system, including regarding devices referred to in point (e)(i) of this paragraph; for those devices, only the latest relevant certificate and, where applicable, any subsequent decision taken by the notified body related to such certificate shall be entered;

(eb) by way of derogation from point (d), first subparagraph, of this paragraph, the obligations to upload the summary of safety and clinical performance in accordance with Article 32(1) and to notify competent authorities in accordance with Article 55(1), through the electronic system referred in Article 33(2), point (d), shall apply to devices referred to in point (e) of this paragraph when the certificate is entered in Eudamed in accordance with point (ea) of this paragraph;

(ec) without prejudice to point (d), first subparagraph, of this paragraph, when a manufacturer is to submit a PSUR in accordance with Article 86(2) of this Regulation, to report a serious incident or a field safety corrective action in accordance with Article 87 of this Regulation, or to submit a trend report in accordance with Article 88 of this Regulation through the electronic system referred to in Article 33(2), point (f), of this Regulation, it shall also register the device, which is the subject of the PSUR or the vigilance reporting, in the electronic system referred to in Article 33(2), points (a) and (b), of this Regulation, except if such device was placed on the market in accordance with Directive 90/385/EEC or 93/42/EEC;';

(d) point (h) is deleted.

Article 2

Amendments to Regulation (EU) 2017/746

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

(1) the following article is inserted:

‘Article 10a

Obligations in case of interruption or discontinuation of supply of certain devices

1. Where a manufacturer anticipates an interruption or a discontinuation of the supply of a device and where it is reasonably foreseeable that such interruption or discontinuation could result in serious harm or a risk of serious harm to patients or public health in one or more Member States, the manufacturer shall inform the competent authority of the Member State where it or its authorised representative is established, as well as the economic operators, health institutions and healthcare professionals to whom it directly supplies the device, of the anticipated interruption or discontinuation.

The information referred to in the first subparagraph shall, other than in exceptional circumstances, be provided at least 6 months before the anticipated interruption or discontinuation. The manufacturer shall specify the reasons for the interruption or discontinuation in the information provided to the competent authority.

2. The competent authority that has received the information referred to in paragraph 1 shall, without undue delay, inform the competent authorities of the other Member States and the Commission of the anticipated interruption or discontinuation.

3. The economic operators who have received the information from the manufacturer in accordance with paragraph 1 or from another economic operator in the supply chain shall, without undue delay, inform any other economic operators, health institutions and healthcare professionals to whom they directly supply the device of the anticipated interruption or discontinuation.';

(2) in Article 74, paragraph 14 is replaced by the following:

‘14. All Member States shall be required to apply the procedure set out in this Article from the date corresponding to 5 years from the date of publication of the notice referred to in Article 34(3) of Regulation (EU) 2017/745, informing that the electronic system referred to in Article 30(2), point (e), of this Regulation is functional and meets the functional specifications drawn up pursuant to Article 34(1) of Regulation (EU) 2017/745.

Before the date set out in the first subparagraph of this paragraph and at the earliest 6 months from the date of publication of the notice referred to in that subparagraph, the procedure set out in this Article shall be applied only by those Member States in which the performance study is to be conducted which have agreed to apply it.’;

(3) Article 110 is amended as follows:

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

‘Certificates issued by notified bodies in accordance with Directive 98/79/EC from 25 May 2017 that were still valid on 26 May 2022 and that have not been withdrawn thereafter shall continue to remain valid after the end of the period indicated on the certificate until 31 December 2027. Certificates issued by notified bodies in accordance with that Directive from 25 May 2017 that were still valid on 26 May 2022 and that have expired before ... [date of entry into force of this amending Regulation] shall be considered to be valid until 31 December 2027 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 54(1) of this Regulation or has required the manufacturer, in accordance with Article 92(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.’;

(c) the following paragraphs are inserted:

‘3a. Devices which have a certificate that was issued in accordance with Directive 98/79/EC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until 31 December 2027.

3b. Devices for which the conformity assessment procedure pursuant to Directive 98/79/EC did not require the involvement of a notified body, for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with that Directive, 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 the following dates:

(a) 31 December 2027, for class D devices;

(b) 31 December 2028, for class C devices;

(c) 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition.

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 98/79/EC;

(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 2025, the manufacturer has put in place a quality management system in accordance with Article 10(8);

(e) 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, no later than:

(i) 26 May 2025, for devices referred to in paragraph 3a and paragraph 3b, point (a), of this Article;

(ii) 26 May 2026, for devices referred to in paragraph 3b, point (b), of this Article;

(iii) 26 May 2027, for devices referred to in paragraph 3b, point (c), of this Article;

(f) the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII no later than:

(i) 26 September 2025, for devices referred to in paragraph 3a and paragraph 3b, point (a), of this Article;

(ii) 26 September 2026, for devices referred to in paragraph 3b, point (b), of this Article;

(iii) 26 September 2027, for devices referred to in paragraph 3b, point (c), of this Article.

3d. By way of derogation from paragraph 3 of this Article, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, and to the registration of economic operators and of devices shall apply to devices referred to in paragraphs 3a and 3b of this Article, instead of the corresponding requirements in Directive 98/79/EC.

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 38 that the latter shall carry out such surveillance.

No later than 26 September 2025, the notified body that has signed the written agreement referred to in paragraph 3c, point (f), of this Article shall become 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 98/79/EC, 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 38 shall be clearly defined in an agreement between the manufacturer and the notified body designated in accordance with Article 38 and, where practicable, the notified body that issued the certificate. The notified body designated in accordance with Article 38 shall not be responsible for conformity assessment activities carried out by the notified body that issued the certificate.';

(d) paragraph 8 is deleted;

(e) the following paragraph is added:

'11. Article 10a shall also apply to devices referred to in paragraphs 3a and 3b of this Article.';

(4) Article 112 is amended as follows:

(a) the first paragraph is replaced by the following:

‘Without prejudice to Article 110(3) to (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 Directive 98/79/EC, that Directive is repealed with effect from 26 May 2022, with the exception of:

(a) Article 11, Article 12(1), point (c), 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 to that Directive, which are repealed, as applicable, with effect from the date referred to in Article 113(3), point (f), of this Regulation in respect of the application of the obligations and requirements that relate to the electronic systems referred to in Article 30(2), points (e) and (f), respectively, of this Regulation;

(b) Article 10, Article 12(1), points (a) and (b), 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 to that Directive, which are repealed, as applicable, with effect from the date referred to in Article 113(3), point (f), of this Regulation in respect of the application of the obligations and requirements that relate to the electronic systems referred to in Article 30(2), points (a) to (d), respectively, of this Regulation.';

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

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

(5) Article 113(3) is amended as follows:

(a) point (a) is deleted;

(b) point (f) is amended as follows:

(i) the first subparagraph is amended as follows:

(1) the introductory wording is replaced by the following:

‘without prejudice to the obligations of the Commission pursuant to Article 34 of Regulation (EU) 2017/745, the obligations and requirements that relate to any of the electronic systems referred to in Article 30(2) of this Regulation shall apply from the date corresponding to 6 months from the date of publication of the notice referred to in Article 34(3) of Regulation (EU) 2017/745, informing that the relevant electronic system is functional and meets the functional specifications drawn up pursuant to Article 34(1) of that Regulation. The provisions referred to in the preceding sentence are:’;

(2) the following indent is inserted after the tenth indent:

‘– Article 51(5),’;

(3) the twelfth indent is replaced by the following:

‘– Article 74(1) to (13), without prejudice to Article 74(14),’;

(4) the final indent is replaced by the following:

‘– Article 110(3d).’;

(ii) the second subparagraph is replaced by the following:

‘Until the date of application of the provisions referred to in the first subparagraph of this point, the corresponding provisions of Directive 98/79/EC regarding information on vigilance reporting, performance studies, registration of devices and economic operators, and certificate notifications shall continue to apply.’;

(c) the following points are inserted:

‘(fa) no later than 6 months from the date set out in point (f), first subparagraph, of this paragraph, manufacturers shall ensure that the information to be entered in Eudamed in accordance with Article 26 is entered in the electronic system referred to in Article 30(2), points (a) and (b), including regarding the following devices, provided that those devices are also placed on the market from the date set out in point (f), first subparagraph, of this paragraph:

(i) devices for which the manufacturer has undertaken a conformity assessment in accordance with Article 48;

(ii) devices placed on the market pursuant to Article 110(3), (3a) or (3b), unless the device, for which the manufacturer has undertaken a conformity assessment in accordance with Article 48, is already registered in Eudamed;

(fb) no later than 12 months from the date set out in point (f), first subparagraph, of this paragraph, notified bodies shall ensure that the information to be entered in Eudamed in accordance with Article 51(5) is entered in the electronic system referred to in Article 30(2), point (d), including regarding devices referred to in point (fa)(i) of this paragraph; for those devices, only the latest relevant certificate and, where applicable, any subsequent decision taken by the notified body related to such certificate shall be entered;

(fc) by way of derogation from point (f), first subparagraph, of this paragraph, the obligations to upload the summary of safety and performance in accordance with Article 29(1) and to notify competent authorities in accordance with Article 50(1), through the electronic system referred in Article 30(2), point (d), shall apply to devices referred to in point (fa) of this paragraph when the certificate is entered in Eudamed in accordance with point (fb) of this paragraph;

(fd) without prejudice to point (f), first subparagraph, of this paragraph, when a manufacturer is to submit a PSUR in accordance with Article 81(2) of this Regulation, to report a serious incident or a field safety corrective action in accordance with Article 82 of this Regulation, or to submit a trend report in accordance with Article 83 of this Regulation through the electronic system referred to in Article 30(2), point (f), of this Regulation, it shall also register the device, which is the subject of the PSUR or the vigilance reporting, in the electronic system referred to in Article 30(2), points (a) and (b), of this Regulation, except if such device was placed on the market in accordance with Directive 98/79/EC;';

(d) point (g) is deleted;

(e) in point (j), the date '26 May 2028' is replaced by '31 December 2030'.

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*.

Article 1, point (1), and Article 2, point (1), shall apply from ... [6 months from the date of entry into force of this amending Regulation].

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

Done at ... , ...

For the European Parliament	*For the Council*
The President	*The President*