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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2021) 627 final
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/746 as regards transitional provisions for certain <i>in vitro</i> diagnostic medical devices and deferred application of requirements for in-house devices

Delegations will find attached document COM(2021) 627 final.

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Brussels, 14.10.2021
COM(2021) 627 final

2021/0323 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and deferred application of requirements for in-house devices

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

Regulation (EU) 2017/746 of the European Parliament and of the Council¹ establishes a new regulatory framework for *in vitro* diagnostic medical devices, such as HIV tests, pregnancy tests or SARS-CoV-2 tests. It is estimated that around 70% of clinical decisions are made using *in vitro* diagnostic medical devices².

The new Regulation (EU) 2017/746 will replace the current Directive 98/79/EC on *in vitro* diagnostic medical devices³ from 26 May 2022 and introduce substantial changes in the sector. The Regulation aims to ensure the smooth functioning of the internal market and a high level of protection of public health, patients and users, taking into account the high number of small and medium-sized enterprises (SMEs) active in this sector.

One of the main changes concerns the involvement of independent conformity assessment bodies ('notified bodies'). Currently, only a relatively small number of high-risk devices (about 8% of all *in vitro* diagnostics on the market) is subject to notified body control under Directive 98/79/EC⁴. Under the Regulation, around 80% of *in vitro* diagnostic medical devices will be under the control of notified bodies, the vast majority of them for the first time⁵. That means that manufacturers will need to apply to a notified body and obtain one or more certificates after completion of the appropriate conformity assessment procedure, before being able to place their devices on the market. On average, a conformity assessment procedure takes around 1 year, after which additional time (around 6 months) is needed to produce the devices and prepare them for release on the market, according to information provided by the medical device industry⁶.

Article 110 of Regulation (EU) 2017/746 contains transitional provisions for devices with a certificate issued by a notified body in accordance with Directive 98/79/EC

¹ 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.

² MedTech Europe Survey Report analysing the availability of *In vitro* Diagnostic Medical Devices (IVDs) in May 2022 when the new EU IVD Regulation applies, 8 September 2021 <https://www.medtecheurope.org/resource-library/medtech-europe-survey-report-analysing-the-availability-of-in-vitro-diagnostic-medical-devices-ivds-in-may-2022-when-the-new-eu-ivd-regulation-applies/> (hereafter referred to as Medtech Europe Survey Report); Rohr U-P, Binder C, Dieterle T, Giusti F, Messina CGM, Toerien E, et al. (2016), *The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report*. PLoS ONE 11(3): e0149856. <https://doi.org/10.1371/journal.pone.0149856>

³ 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.

⁴ Those listed in Annex II to Directive 98/79/EC and devices for self-testing.

⁵ MedTech Europe Survey Report (see footnote 2), p. 4. The impact assessment accompanying the Commission proposal for a Regulation on *in vitro* diagnostic medical devices, COM(2012)541 final, estimated that nearly 90-95% of *in vitro* diagnostic medical devices would fall in classes B, C or D and would therefore be subject to notified body involvement, see SWD(2012)273 final, part III, Annex 2, Sections 4.4 and 4.5.

⁶ Medtech Europe Survey Report (see footnote 2), p. 8.

prior to 26 May 2022. Only devices that require a notified body certificate already under Directive 98/79/EC (around 8%) will benefit from these transitional provisions. This Commission proposal builds on those existing transitional provisions by extending their scope and timelines.

The COVID-19 pandemic has, on the one hand, confirmed the need for a robust regulatory framework for *in vitro* diagnostic medical devices in the EU. For instance, it has illustrated how essential it is for tests placed on the EU market to be accurate, reliable and safe when detecting the presence of viruses such as SARS-CoV-2.

On the other hand, the COVID-19 pandemic and the associated public health crisis have given rise to additional and unprecedented challenges for the implementation of Regulation (EU) 2017/746. These extraordinary circumstances have demanded substantial additional resources from Member States' competent authorities, health institutions, notified bodies, manufacturers and other economic operators to increase the availability of vitally important medical diagnostics. This was due not only to a shift in priorities, new tasks and a significant workload, but also to induced travel restrictions and quarantine orders.

These extraordinary circumstances have had a significant impact on various areas covered by Regulation (EU) 2017/746. Data on market readiness collected by the European Commission during the first half of 2021⁷ show that Member States, health institutions, notified bodies and economic operators will not be in a position to ensure the proper implementation and application of the Regulation from 26 May 2022.

In particular, with only six notified bodies designated⁸ so far under Regulation (EU) 2017/746, there is a grave shortage of notified body capacity, making it impossible for manufacturers to conduct the legally required conformity assessment procedures in time. As the currently designated notified bodies are established in only three countries (Germany, France and the Netherlands), the situation is particularly problematic for SMEs established in other Member States, which have a tendency to apply to notified bodies in their own or neighbouring Member States. In addition, due to COVID-19 travel restrictions, notified bodies were not able to carry out the required on-site audits at the manufacturers' premises to verify the manufacturing and other relevant processes⁹. Travel restrictions are still in place in various regions of the EU and still significantly hamper the proper conduct of conformity assessment by notified bodies.

⁷ In accordance with the Joint implementation and preparedness plan for Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (see below footnote 16), Commission departments requested regular updates from industry and notified bodies on the preparedness of various stakeholders with the aim of detecting possible barriers that could lead to shortages of devices on the market.

⁸ See list of designated notified bodies in the NANDO (new approach notified and designated organisations) information system. https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35

⁹ The Commission Notice on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment (OJ C 8, 11.1.2021, p.1) addresses the possibility to carry out remote audits instead of on-site audits as temporary extraordinary measures taken in response to the exceptional circumstances of the COVID-19 pandemic.

If not addressed, this situation would lead to a significant disruption in the supply of a multitude of *in vitro* diagnostic medical devices on the market both for health institutions and for the public.

The European Parliament, in a cross-party letter of 11 May 2021 signed by several political groups (EPP, S&D, Renew, ECR, GUE/NGL, Greens), and the Council of Health Ministers (EPSCO) of 15 June 2021¹⁰, called on the Commission to present an urgent legislative proposal to smooth the transition to the new regulatory framework and to ensure the availability of *in vitro* diagnostic medical devices on the EU market. Stakeholders representing the medical device industry, notified bodies, healthcare professionals and researchers in the field of clinical chemistry and laboratory medicine, and not-for-profit blood establishments also called for urgent action.

The Commission recognises the need to ensure both a high level of safety and performance of devices, and their availability on the EU market. The proposal therefore aims to extend the existing transitional period for devices covered by a certificate issued under Directive 98/79/EC and to introduce tailored transitional periods for devices that have to undergo a conformity assessment involving notified bodies for the first time under Regulation (EU) 2017/746. As, since its outbreak, many health institutions, in particular hospitals, have had to focus all their efforts on dealing with COVID-19, the Commission proposes to also introduce a transitional period for the requirements for devices manufactured and used within the same health institution ('in-house devices'). This will give health institutions extra time to comply with the new requirements and ensure that in-house tests, which are often essential –especially for rare diseases, can continue to be developed in clinical laboratories¹¹.

- **Consistency with existing policy provisions in the policy area**

Regulation (EU) 2017/746 was adopted together with Regulation (EU) 2017/745 on medical devices¹². In April 2020, due to the extraordinary circumstances caused by the COVID-19 pandemic and to prevent shortages or delays in the supply of medical devices needed for patients and healthcare professionals, the European Parliament and the Council adopted a Regulation¹³ postponing the date of application of Regulation (EU) 2017/745 by 1 year until 26 May 2021, keeping the end date of the transitional period for the validity of certain EC declarations of conformity and

¹⁰ See point 29 of the Council Conclusions on Access to medicines and medical devices for a stronger and resilient EU, approved by the Council (EPSCO) at its meeting of 15 June 2021, 9750/21.

¹¹ According to a study conducted at the university hospital (UZ) Leuven (Belgium), 47% tests used by the clinical laboratory are in house tests, 42% are CE marked tests and 11% are modified or off-label CE marked tests. However nearly 98% of the results were generated with CE marked tests. See Vermeersch P, Van Aelst T, Dequeker EMC. The new IVD Regulation 2017/746: a case study at a large university hospital laboratory in Belgium demonstrates the need for clarification on the degrees of freedom laboratories have to use lab-developed tests to improve patient care. Clin Chem Lab Med. 2020 Jul 21;59(1):101-106. doi: 10.1515/cclm-2020-0804. PMID: 32692695.

¹² 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.

¹³ 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.

notified body certificates issued under the repealed Directives 90/385/EEC and 93/42/EEC as 26 May 2024.

For Regulation (EU) 2017/746, postponing the date of application by 1 year would not resolve the challenges linked to its implementation. As the main challenge to market readiness is the limited notified body capacity, the number of devices that need to undergo a conformity assessment involving a notified body should be spread over a longer period, allowing for a gradual phase-in of the new Regulation's requirements while prioritising high-risk *in vitro* diagnostics. This can be achieved by amending Article 110 of the Regulation on transitional provisions, providing a period for existing higher risk class devices that is shorter than the one for existing lower risk class devices. At the same time, the existing transitional period for devices covered by notified body certificates issued under Directive 98/79/EC should be extended by 1 year until 26 May 2025. This will avoid that the transitional periods under Regulation (EU) 2017/745 and Regulation (EU) 2017/746 end at the same time and lessen the strain on Member States' competent authorities, notified bodies, manufacturers, health institutions and other actors who deal with both medical devices and *in vitro* diagnostics.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The proposal is based on Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU).

- **Subsidiarity**

According to the principle of subsidiarity, EU action may only be taken if the envisaged aims cannot be achieved by Member States alone. The legislation being amended was adopted at EU level in line with the subsidiarity principle and any amendment must be made through an act adopted by the EU legislators. In the case of the current proposal for an amendment, EU action is required to avoid any potential disruption in the supply of devices, to ensure the smooth functioning of the internal market, and to ensure a high level of health protection for patients and users.

- **Proportionality**

The proposed EU action is necessary to ensure that all involved parties fully implement and apply Regulation (EU) 2017/746, taking into account the magnitude of the COVID-19 pandemic and the associated public health crisis. The proposed amendments aim to ensure that the intended purpose of Regulation (EU) 2017/746 can be attained. That purpose is to establish a robust, transparent, predictable and sustainable regulatory framework for *in vitro* diagnostic medical devices, which guarantees a high level of protection of public health and patient safety and the smooth functioning of the internal market for such devices.

The proposal maintains the objective of Regulation (EU) 2017/746 to ensure a high level of safety and performance of devices by enhancing their oversight by notified bodies and, in the case of in-house devices, by setting uniform requirements for health institutions. It only provides for the necessary additional time to achieve this

objective. The proposal is proportionate in that it aims to address the main problem, i.e. that due to shortage of notified body capacity a large number of existing *in vitro* diagnostics may disappear from the market. Therefore, the proposed amendments are limited to allowing a gradual phase-in of the requirements, without altering the substance of Regulation (EU) 2017/746. They focus on existing devices that need notified body involvement and on in-house devices. The proposed amendments will not delay the application of the Regulation to CE marked *in vitro* diagnostic medical devices that do not require the involvement of a notified body (i.e. class A non-sterile devices which represent around 20% of the market¹⁴) and to ‘new’ *in vitro* diagnostics (i.e. those not covered by a certificate or declaration of conformity issued under Directive 98/79/EC). Regulation (EU) 2017/746 is envisaged to apply in full to those devices from 26 May 2022.

The Commission proposes to differentiate between higher (i.e. class D and C devices) and lower (i.e. class B and A sterile devices) risk devices, with shorter transition periods for higher risk devices and longer periods for lower risk ones. This approach aims to balance the available notified body capacity with high level of public health protection.

It also takes into consideration the interest of notified bodies to continue receiving applications for certification, rewarding the investment they have made to be designated under Regulation (EU) 2017/746.

- **Choice of the instrument**

The proposed act is a Regulation to be adopted by the European Parliament and the Council, given that the act to be amended is a Regulation adopted by the European Parliament and the Council.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

This proposal is not accompanied by a separate impact assessment, as an impact assessment was already carried out when preparing Regulation (EU) 2017/746. This proposal does not alter Regulation (EU) 2017/746 in substance and does not impose new obligations on the concerned parties. It primarily aims to amend the transitional provisions, allowing for a progressive rollout of the Regulation’s requirements, for exceptional reasons in the context of the COVID-19 pandemic.

The exceptional circumstances and the need to act quickly to ensure certainty ahead of the Regulation’s application date did not allow for a broad public consultation. The Commission therefore collected the necessary input from Member States and stakeholders through targeted exchanges.

In cooperation with the Medical Device Coordination Group (MDCG)¹⁵, the Commission’s Directorate-General for Health and Food Safety (DG SANTE) drew

¹⁴ MedTech Europe Survey Report, see footnote 2.

¹⁵ The MDCG has been established by Article 103 of Regulation (EU) 2017/745. It is composed of representatives appointed by Member States and chaired by a representative of the Commission. The MDCG

up a joint implementation plan¹⁶ identifying essential and high-priority actions for the implementation of Regulation (EU) 2017/746. The plan includes monitoring activities and contingency planning to address potential bottlenecks and other transitional issues. The plan will be continuously implemented and updated, also after the adoption of the proposed amendment to Regulation (EU) 2017/746.

The market surveys conducted in 2021 demonstrated the need for legislative action. Data available to the Commission, provided by notified bodies and by the trade association MedTech Europe, covering around 90% of the *in vitro* diagnostic market revenue, showed the following situation:

Directive 98/79/EC	Regulation (EU) 2017/746
around 40 000 different <i>in vitro</i> diagnostic medical devices available on the market	around 31 000 different <i>in vitro</i> diagnostic medical devices expected to be available on the market (the industry expects that nearly 9 000 devices currently available on the market will not be CE marked under Regulation (EU) 2017/746, which would be a drop of 22%)
around 3 300 <i>in vitro</i> diagnostic medical devices needed the involvement of a notified body (i.e. about 8% of IVDs on the market) <ul style="list-style-type: none"> • around 2 500 IVDs falling under Annex II to Directive 98/79/EC • around 800 IVDs for self-testing 	over 24 000 <i>in vitro</i> diagnostic medical devices will need the involvement of a notified body (i.e. about 78% of all IVDs expected to enter the market) <ul style="list-style-type: none"> • around 1 200 class D IVDs (=4%) • around 7 860 class C IVDs (=25%) • around 14 890 class B IVDs (=49%) • around 340 class A sterile IVDs (=0.01%)
1 545 certificates issued by notified bodies	31 certificates issued by notified bodies covering roughly 1 300 devices (mainly class B and C devices; no certificates issued for class D devices) ¹⁷ ; around 520 applications for certification received by notified bodies covering roughly

is listed in the Commission's register of expert groups with the code X03565. <https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3565>

¹⁶ Joint implementation and preparedness plan for Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) (June 2021). https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_joint-impl-plan_en.pdf.

¹⁷ The MedTech Europe Survey Report states that 2 848 *in vitro* diagnostic medical devices were covered by certificates, including 156 class D devices, 1 491 class C devices, 1 220 class B devices and 11 class A sterile devices.

	<p>9 600 devices (mainly class B and C devices);</p> <p>for about 95% of IVDs requiring the involvement of a notified body certificates are yet to be issued, including for all class D devices</p> <p>(state of play 9.9.2021)</p>
22 notified bodies designated (18 after UK's withdrawal from the EU)	6 notified bodies designated, 11 applications pending (September 2021)

On 28 January and 27 July 2021, DG SANTE organised meetings with the MDCG to discuss the joint implementation plan, in particular the challenges to implementing the Regulation and the most suitable approach to take for a legislative initiative.

In addition to the regular exchanges with stakeholders throughout the year, targeted discussions on a possible legislative initiative were held in September 2021 with representatives of notified bodies, the European medical device industry, health institutions, health professionals, laboratories, patients and consumers.

Comments received from all those involved have been considered and taken into account to the extent possible while balancing various interests at stake.

The Commission will continue to closely monitor the developments and the impact of the proposed amendments on the market. It will also consult with the MDCG and stakeholders about the need for complementary actions.

4. BUDGETARY IMPLICATIONS

The proposed action has no budgetary implications.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and deferred application of requirements for in-house 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,

After consulting the European Economic and Social Committee,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Regulation (EU) 2017/746 of the European Parliament and of the Council¹ establishes a new regulatory framework to ensure the smooth functioning of the internal market as regards *in vitro* diagnostic medical devices covered by that Regulation, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, Regulation (EU) 2017/746 sets high standards of quality and safety for *in vitro* diagnostic medical devices in order to meet common safety concerns as regards such devices. Furthermore, Regulation (EU) 2017/746 significantly reinforces key elements of the existing regulatory approach in Directive 98/79/EC of the European Parliament and of the Council², such as the supervision of notified bodies, conformity assessment procedures, performance evaluation and performance studies, vigilance and market

¹ 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).

² 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).

surveillance, whilst introducing provisions ensuring transparency and traceability regarding *in vitro* diagnostic medical devices.

- (2) The COVID-19 pandemic and the associated public health crisis presented and still presents an unprecedented challenge to Member States and constitutes an immense burden for national authorities, health institutions, Union citizens, notified bodies and economic operators. The public health crisis has created extraordinary circumstances that demand substantial additional resources, as well as increased availability of vitally important *in vitro* diagnostic medical devices, that could not reasonably have been anticipated at the time of adoption of Regulation (EU) 2017/746. Those extraordinary circumstances have a significant impact on various areas covered by that Regulation, such as the designation and work of notified bodies and the placing on the market and making available on the market of *in vitro* diagnostic medical devices in the Union.
- (3) *In vitro* diagnostic medical devices are essential for the health and safety of Union citizens and SARS-CoV-2 tests, in particular, are vital for the fight against the pandemic. Therefore, it is necessary to ensure an uninterrupted market supply of such devices in the Union.
- (4) Given the unprecedented magnitude of the current challenges, the additional resources needed from Member States, notified bodies, economic operators, health institutions and other relevant parties in order to fight the COVID-19 pandemic and the current limited capacity of notified bodies, and taking into account the complexity of Regulation (EU) 2017/746, it is very likely that Member States, health institutions, notified bodies, economic operators and other relevant parties will not be in a position to ensure the proper implementation and full application of that Regulation from 26 May 2022 as laid down therein.
- (5) Moreover, the current transitional period provided for in Regulation (EU) 2017/746 regarding the validity of certificates issued by notified bodies for *in vitro* diagnostic medical devices under Directive 98/79/EC will end on the same day as the transitional period provided for in Regulation (EU) 2017/745 of the European Parliament and of the Council³ regarding the validity of certain EC declarations of conformity and certificates issued by notified bodies for medical devices under the repealed Council Directives 90/385/EEC⁴ and 93/42/EEC⁵, that is on 26 May 2024. This puts a strain on actors who deal with both medical devices and *in vitro* diagnostic medical devices.
- (6) In order to ensure the smooth functioning of the internal market and a high level of protection of public health and patient safety, as well as to provide legal certainty and avoid potential market disruption, it is necessary to extend the transitional periods laid down in Regulation (EU) 2017/746 for devices covered by certificates issued by notified bodies under Directive 98/79/EC. For the same reasons, it is also necessary to provide a sufficient transitional period for devices which are to undergo conformity

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 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).

⁵ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p.1).

assessment involving a notified body for the first time under Regulation (EU) 2017/746.

- (7) For the period of time needed to expand the capacity of notified bodies, a balance should be struck between the limited available capacity and a high level of public health protection. Therefore, the transitional periods for *in vitro* diagnostic medical devices that are to undergo conformity assessment involving a notified body for the first time under Regulation (EU) 2017/746 should differentiate between higher and lower risk devices. The length of the transitional period should depend on the risk class of the device concerned so that the period is shorter for devices of a higher risk and longer for devices of a lower risk class.
- (8) In order to allow *in vitro* diagnostic medical devices which are placed on the market in accordance with the transitional provisions laid down in this Regulation sufficient time to be further made available on the market, including to be supplied to the end users, or to be put into service, the sell-off date provided for in Regulation (EU) 2017/746 should be adapted to take into account the additional transitional periods.
- (9) Having regard to the resources required from health institutions in the fight against the COVID-19 pandemic, those institutions should be given additional time to prepare for the specific requirements laid down in Regulation (EU) 2017/746 for the manufacture and use of devices within the same health institution ('in-house devices'). The application of those requirements should therefore be deferred. As the health institutions will need a complete overview of CE marked *in vitro* diagnostic medical devices available on the market, the requirement to provide justification that the target patient group's needs cannot be met, or cannot be met at the appropriate level of performance, by a device available on the market should not become applicable until the transitional periods laid down in this Regulation have ended.
- (10) Regulation (EU) 2017/746 should therefore be amended accordingly.
- (11) Since the objectives of this Regulation, namely to extend the transitional periods set out in Regulation (EU) 2017/746, to introduce additional transitional provisions in that Regulation and to defer the application of the provisions of that Regulation concerning in-house devices, 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.
- (12) The adoption of this Regulation takes place under exceptional circumstances arising from the COVID-19 pandemic and the associated public health crisis. To attain the intended effect of amending Regulation (EU) 2017/746 as regards the transitional periods and the date of application of the provisions on in-house devices, in particular in view of providing legal certainty for economic operators, it is necessary for this Regulation to enter into force before 26 May 2022. It was therefore considered appropriate to provide for an exception to the eight-week period referred to 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.

- (13) In light of the overriding need to immediately address the public health crisis associated with the COVID-19 pandemic, 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*,

HAVE ADOPTED THIS REGULATION:

Article 1

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

(1) Article 110 is amended as follows:

(a) paragraph 2 is amended as follows:

- (i) in the first subparagraph, the date ‘27 May 2024’ is replaced by ‘27 May 2025’;
- (ii) in the second subparagraph, the date ‘27 May 2024’ is replaced by ‘27 May 2025’;

(b) paragraphs 3 and 4 are replaced by the following:

- ‘3. By way of derogation from Article 5 of this Regulation, the devices referred to in the second and third subparagraphs of this paragraph may be placed on the market or put into service until the dates set out in those subparagraphs, provided that from the date of application of this Regulation they continue to comply with Directive 98/79/EC and provided that there are no significant changes in the design and intended purpose.

Devices 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 be placed on the market or put into service until 26 May 2025.

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) 26 May 2025 for class D devices;
- (b) 26 May 2026 for class C devices;
- (c) 26 May 2027 for class B devices;
- (d) 26 May 2027 for class A devices placed on the market in sterile condition.

However, 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 the first, second and third subparagraph instead of the corresponding requirements in Directive 98/79/EC.

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

4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022 may continue to be made available on the market or put into service until 26 May 2025.

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 until the following dates:

- (a) 26 May 2026 for devices referred to in paragraph 3, second subparagraph, or in paragraph 3, third subparagraph, point (a);
- (b) 26 May 2027 for devices referred to in paragraph 3, third subparagraph, point (b);
- (c) 26 May 2028 for devices referred to in paragraph 3, third subparagraph, points (c) and (d).’;

- (2) in Article 112, second subparagraph, the date ‘27 May 2025’ is replaced by ‘26 May 2028’;
- (3) in Article 113(3), the following points (i) and (j) are added:
 - ‘(i) Article 5(5), points (b), (c) and (e) to (i), shall apply from 26 May 2024;
 - (j) Article 5(5), point (d), shall apply from 26 May 2028.’.

Article 2

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 Brussels,

For the European Parliament
The President

For the Council
The President