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Delegations will find attached document COM(2024) 43 final.

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EUROPEAN
COMMISSION

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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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Regulation (EU) 2017/745 (the ‘Medical Devices Regulation’ (MDR))¹ and Regulation (EU) 2017/746 (the ‘*In Vitro* Diagnostic Medical Devices Regulation’ (IVDR))² of the European Parliament and of the Council set a strengthened regulatory framework for medical devices and *in vitro* diagnostic medical devices (IVDs). Their objectives are a high level of protection of health for patients and users and the smooth functioning of the single market for these products. To achieve these objectives and to address issues identified with the previous regulatory framework, the Regulations set up a more robust system of conformity assessment to ensure the quality, safety and performance of devices placed on the EU market.

The MDR has applied since 26 May 2021³. The transitional period provided for in Article 120 has been extended by Regulation (EU) 2023/607⁴ and will end on either 31 December 2027 or 31 December 2028, depending on the device’s risk class and subject to certain conditions.

The IVDR has applied since 26 May 2022. In January 2022, the European Parliament and the Council adopted a staggered extension of its transitional period, ranging from 26 May 2025 for high-risk IVDs to 26 May 2027 for lower-risk IVDs, and to 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions⁵. This extension was not subject to conditions similar to the ones laid down for medical devices by Regulation (EU) 2023/607.

This proposal for targeted amendments addresses two urgent issues. Firstly, it aims to further extend the transitional period for certain IVDs to mitigate the risk of shortages of these products, especially of high-risk IVDs, which are used, for example, to test for infections in blood or organ donations or for blood grouping for transfusions.

Secondly, the proposal aims to enable a gradual roll-out of the electronic systems integrated into the European database on medical devices (‘Eudamed’) that are finalised, instead of deferring the mandatory use of Eudamed until the last of the six

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

² Regulation (EU) 2017/746 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).

³ 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) had postponed the date of application of Regulation (EU) 2017/745 from 26 May 2020 to 26 May 2021 due to the COVID-19 outbreak and the associated public health crisis.

⁴ Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices (OJ L 80, 20.3.2023, p. 24).

⁵ Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of conditions for in-house devices (OJ L 19, 28.1.2022, p. 3).

modules is completed. The use of Eudamed – and especially its systems for the registration of economic operators, devices and certificates – will improve transparency and provide information on devices on the EU market, helping to monitor the availability of devices.

In addition, the proposal aims to impose a requirement on manufacturers to give prior notice before interrupting the supply of certain critical medical devices and IVDs.

a) Transition of devices to the IVDR

There is a wide variety of IVDs, including HIV tests for blood donation screening or individual diagnosis, cancer tests, pregnancy tests or SARS-CoV-2 tests. Around two thirds of all clinical decisions are based on information provided by IVDs⁶. It is paramount to ensure both a high level of safety and performance of IVDs and their availability to healthcare systems.

The IVDR has introduced very substantial changes to the regulatory framework for IVDs with significant resource and capacity implications. According to the IVDR, IVDs are classified into different risk classes from class A (low risk) to class D (high risk). One of the most profound changes is the increased involvement of independent conformity assessment bodies (‘notified bodies’) in conformity assessment, in a way that is proportionate to the device’s risk class. Under the previous Directive 98/79/EC⁷, only a relatively small number of high-risk devices, i.e. about 8% of the more than 40 000 IVDs on the EU market covered by the Directive⁸, were subject to scrutiny by notified bodies. In October 2022, there were 1 551 valid certificates issued by notified bodies under Directive 98/79/EC⁹. Some of these have already expired (38 in 2022 and 165 in 2023); 482 certificates will expire in 2024 and 866 certificates will expire in 2025 (by 26 May)¹⁰.

Under the IVDR, around 80% of IVDs will be subject to scrutiny by notified bodies, most of them for the first time⁸. As a consequence, the number of certificates under the IVDR is expected to be significantly higher than the number of certificates issued under Directive 98/79/EC. The relationship between the number of devices and the number of certificates covering them is complex, so no precise calculation can be made, but numbers in the order of 15 000 certificates and higher could reasonably be expected. More than 1 000 devices are in the highest risk class (class D)¹¹. Under the IVDR, these devices require the issuance of both a quality management system certificate and an individual device technical documentation assessment certificate.

⁶ Rohr, Ulrich-Peter, et al., ‘The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report’, *PLOS ONE* 11(3): e0149856 (2016).

⁷ 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).

⁸ *MedTech Europe Survey Report – Analysing the availability of In vitro Diagnostic Medical Devices (IVDs) in May 2022 when the new EU IVD Regulation applies*, <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/>.

⁹ Based on data received from notified bodies in October 2022.

¹⁰ Based on data received from notified bodies in October 2022.

¹¹ *Transition to the IVD Regulation – MedTech Europe Survey Results for October 2022*, https://www.medtecheurope.org/wp-content/uploads/2023/02/230220_public-report-ivdr-survey_di35.pdf.

Those figures are in stark contrast to the low number of certificates already issued and ongoing applications under the IVDR. In fact, the vast majority of IVDs have not yet transitioned to the IVDR. As of end of October 2023, manufacturers had submitted 1 378 applications for conformity assessment under the IVDR, resulting in 677 certificates issued by notified bodies across all risk classes. For class D IVDs, only 335 applications had been submitted and 117 certificates had been issued¹².

While there are still several years of transitional period remaining for classes C, B and A sterile, the transitional period for class D devices ends on 26 May 2025. Given the low number of certificates and applications for class D IVDs, and the long duration of the conformity assessment process as explained below, there is a high risk of shortages of many of these devices. Class D devices are used, for example, to test for infections in blood or organ donations, to test patients for life-threatening infectious diseases, or for blood grouping for transfusions. Therefore, there is a high risk of a public health crisis if there is a shortage of such devices.

As explained above, in January 2022, the European Parliament and the Council adopted a staggered extension of the transitional period due to the impact of the COVID-19 pandemic. The slow rate of transition has made this extension insufficient. The reasons are multifaceted; however, they are underpinned by the far-reaching nature of changes introduced by the IVDR and the resulting increased need for scientific, technical and regulatory expertise and capacity at all levels in the system, which require time to be built up.

At present, only 12 notified bodies¹³ are designated under the IVDR, compared to 22 notified bodies designated under Directive 98/79/EC (18 after the UK's withdrawal from the EU). A further 8 applications for designation as notified body are currently in progress. The staggering of the transitional periods by risk class in 2022 meant that the workload on notified bodies could be distributed over time, and provided relief to the sector¹⁴. Nevertheless, access to notified bodies has remained an issue, especially for small to medium-sized enterprises (SMEs)¹¹.

Notified bodies are also facing challenges due to the extensive changes introduced by the IVDR. They must apply new requirements for types of devices that they have not handled previously. The duration of the notified body's assessment is affected by the often insufficient quality of manufacturers' applications¹⁵. As of July 2023, the average duration of the conformity assessment process combining quality management system and technical documentation assessment was around 18 months¹⁵.

Thus, the overall notified body capacity in the EU is limited, due to both low numbers of notified bodies and challenges to their efficient and smooth operation. Additional transition time is needed to help address this persisting problem. More

¹² Based on preliminary data received from notified bodies in December 2023.

¹³ See list of designated notified bodies in the NANDO (new approach notified and designated organisations) information system, [EUROPA – European Commission – Growth – Regulatory policy - SMCS](#).

¹⁴ The MedTech Europe survey indicates that ~91% of companies report having benefited from the change in IVDR transitional periods in early 2022. *Transition to the IVD Regulation – MedTech Europe Survey Results for October 2022*, https://www.medtecheurope.org/wp-content/uploads/2023/02/230220_public-report-ivdr-survey_di35.pdf.

¹⁵ Notified bodies survey on certifications and applications, https://health.ec.europa.eu/system/files/2023-11/md_nb_survey_certifications_applications_en.pdf.

notified bodies will be designated over time and the efficiency in processing applications will improve as both manufacturers and notified bodies gain more experience with the IVDR. In the short term, it is also important to maintain the staggering of transitional periods by risk class to avoid a bottleneck at the level of notified bodies.

Furthermore, it appears that many manufacturers are not sufficiently prepared to demonstrate compliance with the requirements of the IVDR. This may be due to various causes, including the complexity of these new requirements, lack of experience of interaction with notified bodies, and the continuous development of the IVDR framework, such as ongoing designation of notified bodies, and for class D IVDs adoption of common specifications and designation of EU reference laboratories. Around 90% of medical device companies are SMEs¹⁶, for which managing the transition can be especially challenging. More and more tools are being put in place to support manufacturers, with particular attention to SMEs, including: (i) guidance by the Medical Device Coordination Group (MDCG) and by notified bodies; (ii) webinars and training by notified bodies; (iii) structured dialogue with notified bodies¹⁷; or (iv) EU-funded work to make notified body capacity more visible¹⁸. Additional transition time is necessary to allow manufacturers to make greater use of these tools and therefore support the transition of their devices to the IVDR.

This proposal aims to mitigate the risk of shortages of IVDs by giving manufacturers and notified bodies more time, under certain conditions, to complete the necessary conformity assessment procedures, without lowering the requirements.

The need for additional time is most acute for mitigating shortages of class D devices. They constitute about 4% of the market¹⁶ but their conformity assessment is intensive due to the requirement for individual technical documentation assessment and, where relevant, involvement of the scientific bodies (expert panel and EU reference laboratories). With only 12 notified bodies currently designated, capacity in the system to perform the required third party assessments remains limited, so an extension of the transitional period for class D IVDs should be combined with a shift in the transition deadlines for the other device groups as well to avoid a bottleneck in the certification process and to prevent shortages of these devices too. Class C and class B are large device groups (representing 26% and 49% of the market, respectively), and some of them are also subject to special requirements such as individual technical documentation assessment. It is also logical from the perspective of protection of public health that higher risk classes should be subject to the more stringent rules earlier than lower risk classes.

The extension should be subject to conditions to support the transition to the IVDR, similar to the approach adopted in Regulation (EU) 2023/607, which extended the MDR transitional period. These conditions will ensure that only manufacturers that are actively taking the necessary steps to transition to the new rules and continue to place on the market devices meeting high safety standards will benefit from the additional time. In addition, at the latest by 26 May 2025, all manufacturers will have

¹⁶ https://www.medtecheurope.org/wp-content/uploads/2023/10/the-european-medical-technology-industry-in-figures_2023-1.pdf

¹⁷ See action 15 in MDCG position paper [MDCG 2022-14](#), *Transition to the MDR and IVDR – Notified body capacity and availability of medical devices and IVDs* (August 2022).

¹⁸ <https://nobocap.eu/>

to put in place a quality management system in accordance with Article 10(8) IVDR. Such an approach respects the work of those manufacturers that have already taken the necessary steps to comply with the IVDR.

Finally, it is clear that an extension of the transitional period will provide only a short-term solution to mitigate the risk of shortages. It will not solve certain underlying structural problems related to the implementation of the IVDR, notably with regard to the specific situation of SMEs. Moreover, the transition must be completed to ensure the credibility and robustness of the EU medical device regulatory system and to provide the necessary legal certainty for a stable, innovative and safe environment. It is necessary to analyse problems related to the implementation of the IVDR and the MDR, and their root causes, to identify shortcomings of the regulatory framework and remedy them in the medium term with a view to ensuring patient safety and access to safe and performant devices in a sustainable manner.

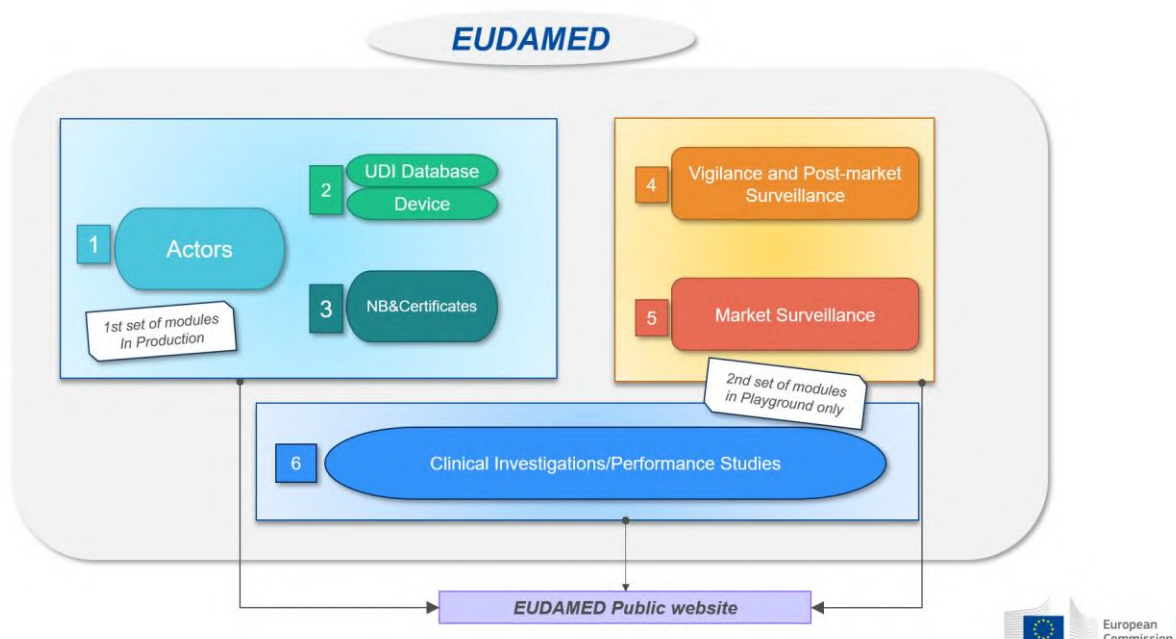
b) European database on medical devices (Eudamed)

In accordance with Article 33 MDR and Article 30 IVDR, the Commission must set up, maintain and manage the European database on medical devices (Eudamed). Eudamed must include seven electronic systems including the UDI database¹⁹. It is being developed in accordance with functional specifications drawn up by the Commission in collaboration with the MDCG and endorsed by the MDCG. Pursuant to these specifications, Eudamed will consist of six modules²⁰, covering all the features specified by the Regulations: UDI/Devices, Actors, Notified bodies/Certificates, Post-Market Surveillance and Vigilance, Market Surveillance, and Clinical investigations/Performance studies.

Three Eudamed modules have been available for voluntary use since December 2020 (Actors) and October 2021 (UDI/Devices; Notified bodies/Certificates). Two further modules (Market Surveillance; Post-Market Surveillance and Vigilance) are expected to be completed in Q2/2024. The last module (Clinical investigations/Performance studies) will not be completed before Q3/2026. Pursuant to the current MDR rules, Eudamed can only be used mandatorily from a certain date after the Commission has verified that Eudamed is fully functional and has published a notice to that effect. Therefore, the delayed development of the last module holds back the mandatory use of the electronic systems that have been completed already. The mandatory use of all six modules thus cannot be expected before Q4/2027, with additional transitional periods not ending before Q2/2029.

¹⁹ UDI stands for unique device identification. The UDI system and the UDI database are being set up in accordance with Articles 27 and 28 MDR.

²⁰ The electronic systems for registration of devices and for the UDI database are merged into one UDI/Devices module to increase efficiency. As a consequence, Eudamed is composed of six modules.



However, the use of Eudamed is key for effective and efficient implementation of the MDR and IVDR and of high value to the work of the competent authorities and the Commission in monitoring the market. Moreover, the deployment of Eudamed has profound and beneficial implications in terms of resource savings for manufacturers as it prevents multiple registrations or instances of communication of data at national level. This proposal aims to enable a gradual implementation of individual Eudamed modules once they have been audited and declared functional. Mandatory use of several modules could then start as early as Q4/2025. Consequently, also the specific transitional provisions in the MDR and IVDR related to Eudamed need to be amended to enable a smooth progressive transfer from multiple registrations in national databases to a single registration in Eudamed.

In addition, having regard to the delay in the development of the module for clinical investigations / performance studies, the timelines for the application of the coordinated assessment of clinical investigations and performance studies need to be adapted. Keeping the approach provided for in the MDR and the IVDR, the coordinated assessment should first be applied by Member States on an 'opt-in' basis. Five years after its voluntary application, the coordinated assessment should become mandatory for all Member States.

c) Prior notice if supply of certain medical devices and *in vitro* diagnostic medical devices is stopped

Healthcare professionals, industry and competent authorities have reported that during the transitional period of the MDR and the IVDR, the supply of many medical devices and IVDs has or is likely to be stopped. In certain cases, especially if no or few alternative devices are available, the interruption of supply can result in serious harm or a risk of serious harm to patients or public health.

This proposal aims to impose an obligation on manufacturers to inform their relevant competent authority and health institutions before they cease, temporarily or permanently, the supply of a critical device. If manufacturers do not supply directly to health institutions or healthcare professionals, they should inform the relevant economic operators in the supply chain, which then can inform the health

institutions. This mechanism will enable the authority and health institutions to consider mitigating measures to ensure patient health and safety. In accordance with Article 105 MDR, the MDCG may decide to provide guidance with the aim to ensure effective and harmonised implementation of this prior notice mechanism.

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

The proposal is consistent with existing policy provisions as well as ongoing non-legislative measures, which will supplement the proposed amendment. To avert the risk of shortages of medical devices, the European Parliament and the Council adopted in March 2023 Regulation (EU) 2023/607²¹ extending the MDR transitional period until 31 December 2027 or 31 December 2028, depending on the device's risk class and subject to certain conditions. On 25 August 2022, the MDCG endorsed its position paper [MDCG 2022-14](#)²². The paper sets out 19 non-legislative measures with a view to increasing notified body capacity, access to notified bodies, and manufacturers' preparedness. This should support a successful transition to the MDR and IVDR. Several of the measures listed in [MDCG 2022-14](#) have already been implemented, such as a MDCG position paper on hybrid audits²³, new MDCG guidance on appropriate surveillance²⁴, and a revision of MDCG 2019-6, removing obstacles to the employment of qualified personnel by notified bodies²⁵.

On 1 December 2022, the Commission adopted two delegated acts deferring the first complete reassessment of notified bodies²⁶. This has freed up capacity of both designating authorities and notified bodies.

Work is ongoing to implement the remaining measures listed in MDCG 2022-14, as they remain important also under an extended transitional period. Measures to support the implementation of the two Regulations are regularly (co-)funded under annual work programmes of the EU4Health Programme²⁷. Among other measures, in

²¹ Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices (OJ L 80, 20.3.2023, p. 24).

²² MDCG position paper [MDCG 2022-14](#), *Transition to the MDR and IVDR – Notified body capacity and availability of medical devices and IVDs* (August 2022).

²³ [MDCG 2022-17](#), *MDCG position paper on 'hybrid audits'* (December 2022).

²⁴ [MDCG 2022-15](#), *Guidance on appropriate surveillance regarding the transitional provisions under Article 110 IVDR with regard to devices covered by certificates according to the IVDD* (September 2022); [MDCG 2022-4 rev. 1](#), *Guidance on appropriate surveillance regarding the transitional provisions under Article 120 MDR with regard to devices covered by certificates according to the MDD or the AIMDD* (December 2022).

²⁵ [MDCG 2019-6 Rev.4](#), *Questions and answers: Requirements relating to notified bodies* (October 2022).

²⁶ Commission Delegated Regulation (EU) 2023/502 of 1 December 2022 amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the frequency of complete reassessments of notified bodies (OJ L 70, 8.3.2023, p. 1); Commission Delegated Regulation (EU) 2023/503 of 1 December 2022 amending Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the frequency of complete reassessments of notified bodies (OJ L 70, 8.3.2023, p. 3).

²⁷ E.g. under the 2022 [EU4Health work programme](#): a call for proposals aiming to foster capacity building of existing and new notified bodies, to facilitate access of SMEs and first-time applicants to notified bodies, and to increase preparedness of manufacturers (see HS-g-22-19.03); various measures supporting the implementation of the MDR and the IVDR (see HS-p-22-19.04, 06, 07, 08, 09, 10 and 11); and direct grants for Member State authorities: strengthened market surveillance of medical devices and *in vitro* diagnostic medical devices (HS-g-22-19.01). Under the [2023 EU4Health work programme](#): support to the technical secretariat of the Notified Bodies Coordination Group (see HS-p-

April 2023, the Commission has ordered a study on regulatory governance and innovation, which should provide preliminary results in Q3/2024.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

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

- **Subsidiarity (for non-exclusive competence)**

According to the principle of subsidiarity, EU action may only be taken if the aims of the envisaged measure 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. As regards the current proposal for an amendment, EU action is required to: (i) avoid any potential disruption in the supply of IVDs; (ii) enable timely use of completed Eudamed modules; (iii) ensure the smooth functioning of the single market; and (iv) ensure a high level of health protection for patients and users.

- **Proportionality**

The proposed EU action is necessary to mitigate the risk of shortages of IVDs across the EU and the serious impact of such shortages on public health. The proposed targeted amendments thus aim to help achieve the intended purpose of the MDR and the IVDR. This purpose is to set a robust, transparent, predictable and sustainable regulatory framework for medical devices and IVDs that guarantees a high level of protection of public health and patient safety and the smooth functioning of the single market for these products.

The proposal maintains the objective of the IVDR to ensure a high level of safety and performance of devices by strengthening their scrutiny by notified bodies. It provides the additional time needed to build the necessary capacity and expertise to achieve this objective, while safeguarding a high level of protection of public health and patient safety.

The proposal is proportionate in that it aims to address the identified issue, i.e. that due to shortage of notified body capacity and insufficient preparedness among manufacturers, a large number of existing IVDs may disappear from the market. Therefore, the proposed amendments to the IVDR are limited to enabling a gradual implementation of the requirements, limited to ‘legacy’ devices²⁸ that require notified body involvement in the conformity assessment, without changing the substance of these requirements. In addition, the extension of the transitional period is subject to conditions that set milestones for manufacturers and help them and notified bodies structure the transition. The Commission proposes to differentiate between higher-risk devices (i.e. class D) and medium- to lower-risk devices (i.e.

23-63); and call for proposals for a programme on orphan medical devices, in particular targeting paediatric patients (see HS-g-23-65). Under the [2024 EU4Health work programme](#): support to Eudamed (see HS-p-24-62); and studies supporting the evaluation of the MDR and the IVDR (HS-p-24-65).

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The term ‘legacy’ devices refers to devices placed on the market after the IVDR’s date of application in accordance with its transitional provisions in Article 110. For further explanations see [MDCG 2022-8, Regulation \(EU\) 2017/746 - application of IVDR requirements to ‘legacy devices’ and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC](#) (May 2022).

class C, class B and class A sterile), with shorter transitional periods for higher-risk devices and longer periods for lower-risk ones. This approach aims to balance the available notified body capacity and manufacturers' level of preparedness with a high level of public health protection.

As regards Eudamed, the proposal is proportionate as it enables faster achievement of the objective to increase transparency of the regulatory system.

- **Choice of the instrument**

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

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

- ***Ex post* evaluations / fitness checks of existing legislation**

Given the urgent nature of this proposal and the limited changes related only to the gradual roll-out of Eudamed and the extension of the IVDR transitional period, it is not accompanied by a dedicated impact assessment. An impact assessment was already carried out when preparing the proposals for the MDR and the IVDR, and this proposal does not alter the MDR or IVDR in substance and does not impose new obligations on the concerned parties. It primarily aims to amend the transitional provisions, giving, under certain conditions, additional time to transition to the IVDR's requirements to avoid shortages and protect public health in the EU. By enabling an earlier mandatory use of available Eudamed modules, sometimes multiple national registrations or notifications will be replaced by a single registration/notification at EU level. The proposal will also increase transparency and traceability of medical devices and IVDs, facilitating monitoring of their availability and their safe performance by national competent authorities via EU-wide electronic means. The need to act quickly to ensure certainty ahead of the end of the IVDR's current transitional period made it impossible to carry out a broad public consultation. Therefore, the Commission collected the necessary input from Member States and stakeholders through targeted exchanges.

Input from Member State authorities and stakeholders has been sought through targeted interaction, mainly during the MDCG meetings on 10-11 October and 11-12 and 18 December 2023 and related discussions in MDCG subgroups. An extraordinary MDCG meeting with stakeholders was held on 20 December 2023 to discuss issues related to possible amendments. An exchange of views with Member States took place on 30 November 2023 during the EPSCO Health Council.

The Commission will continue to closely monitor the progress in the implementation of the Regulations and the impact of the proposed amendments. It will also consult with the MDCG and stakeholders about the need for supplementary action.

In accordance with Article 121 MDR and Article 111 IVDR, the Commission is required to assess the application of the Regulations and produce an evaluation report at the latest by 27 May 2027. Having regard to the multiple challenges related to the implementation of the two Regulations, the Commission will start preparatory works for a targeted evaluation already in 2024. The targeted evaluation will assess in particular whether the legislation has delivered results as intended, and whether it is (still) fit for purpose or underperforming in ensuring availability of devices for small

patient populations (i.e. ‘orphan devices’) and fostering the development and availability of innovative devices in the EU. The implementation of the prior notice mechanism for monitoring device shortages will deserve special attention in the assessment, as well as costs and administrative burdens stemming from the implementation of the legislation, especially for SMEs.

4. BUDGETARY IMPLICATIONS

The proposed action has no budgetary implications

5. OTHER ELEMENTS

- **Detailed explanation of the specific provisions of the proposal**

Article 1: amendments to the MDR

Article 1 introduces a new Article 10a laying down an obligation on manufacturers to give prior notice about interruption of supply of certain critical medical devices. Besides notification to the relevant competent authorities, manufacturers should also inform health institutions or healthcare professionals and economic operators to whom they directly supply the device. The relevant economic operators should provide the information in the downstream supply chain until it reaches the health institutions or healthcare professionals. This mechanism will enable the authority and health institutions to consider mitigating measures to ensure patient health and safety.

It also amends several provisions related to Eudamed. The changes to Article 34(1) and (2) remove the concept that the use of Eudamed can only become mandatory when all its modules have been declared fully functional. Instead, the new wording of the provisions enable a gradual implementation of individual Eudamed modules once they have been audited and declared functional.

As the application of the coordinated assessment of clinical investigations depends on the functionality of the Eudamed module on clinical investigations / performance studies, the timeline for the application of the coordinated assessment has been adapted in Article 78(14). The approach is kept that the coordinated assessment procedure should, during the first five years, apply only to Member States on an ‘opt-in’ basis, before it will become mandatory for all Member States.

Consequently, also the specific transitional provisions in Article 120(8), Article 122 and Article 123(3) related to Eudamed are amended to enable a smooth progressive transfer from multiple registrations in national databases to a single registration in Eudamed. The amendments make sure that national registration requirements end when the registration requirements in Eudamed start to apply. Moreover, the changes clarify which devices and which certificates must be registered in Eudamed and in which timeframe.

Article 2: amendments to the IVDR

Article 2 contains the amendments to the IVDR, which mirror to a large extent the changes made to the MDR. A new Article 10a provides for a prior notice mechanism when a manufacturer anticipates the interruption of supply of certain critical *in vitro* diagnostic medical devices. The provisions concerning the timing of the application of the coordinated assessment of performance studies (Article 74(14)) and the

specific transitional provisions related to Eudamed in Article 110(8), Article 112 and Article 113(3) are amended in a similar way as it is done in the MDR.

In addition, Article 110(2) and (3) are amended to extend the IVDR's transitional periods. For that purpose, the changes in Article 110(2) extend the validity of certificates issued under Directives 98/79/EC that were valid on the day of the IVDR's date of application (26 May 2022) and have not been withdrawn by a notified body. The extension is directly applicable, so that notified bodies are not required to change the date on the individual certificates. The length of the extension of the certificate's validity corresponds to the length of the extended transitional period laid down in the proposed Article 110(3) to (3b). As regards certificates that have already expired when the proposed amendment comes into force, the extension will be subject to the condition that, at the moment of the expiry, the manufacturer has signed a contract with a notified body for the conformity assessment of the device in question. Alternatively, if no such contract has been signed at the moment when the certificate expired, a national competent authority may have granted a derogation from the applicable conformity assessment procedure in accordance with Article 54 or have required the manufacturer to carry out the conformity assessment procedure within a specific time period in accordance with Article 92.

The changes to Article 110(3) extend the transitional periods that are applicable to 'legacy devices', i.e. those covered by a certificate or declaration of conformity issued under Directive 98/79/EC before 26 May 2022. Due to the length of the provision, paragraph 3 is replaced by paragraphs 3 to 3e. The staggering of the transition periods is kept, extending the timeline until 31 December 2027 for IVDs covered by a certificate that was issued in accordance with Directive 98/79/EC and for class D devices, until 31 December 2028 for class C devices and until 31 December 2029 for class B and A sterile devices.

Moreover, the application of the extended transition period is subject to several cumulative conditions, which are:

- the devices must continue to comply with Directive 98/79/EC. This condition is already part of the current Article 110(3);
- the devices do not undergo significant changes in the design and intended purpose. This condition is already part of the current Article 110(3);
- 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. The concept of "unacceptable risk to health and safety" is set out in Article 89 and 90 of the IVDR. No systematic check of the device's safety is required, as devices covered by a certificate issued under Directive 98/79/EC will be under 'appropriate surveillance' by the body that issued the certificate or a notified body designated under the IVDR. Where, as part of their market surveillance activities, a competent authority finds that a device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, the transition period ceases to apply for that device;
- no later than 26 May 2025, the manufacturer has put in place a quality management system (QMS) in accordance with Article 10(8) of the IVDR. This condition aims to ensure that manufacturers gradually move towards full compliance with the IVDR requirements. No specific attestation, i.e. no self-

declaration nor verification of the appropriateness of the QMS by a notified body, is required at this stage;

- by a specific date (26 May 2025, 26 May 2026 or 26 May 2027, depending on the risk class), the manufacturer, or its authorised representative, has lodged a formal application in accordance with Annex VII, Section 4.3, of the IVDR for conformity assessment in respect of the ‘legacy device’ covered by a Directive’s certificate or declaration of conformity, or in respect of a device intended to substitute that device under the IVDR. Within four months, such an application must be covered by a written agreement between the notified body and the manufacturer. This condition aims to ensure that only devices that the manufacturer intends to transition to the IVDR will benefit from the extended transition period. The extension should, however, also apply to ‘legacy devices’ that the manufacturer intends to replace by a ‘new’ device for which it applies for conformity assessment before the relevant deadline set in Article 110(3c). In this way, unnecessary applications for certification of devices that will in any case be phased out and replaced by a new generation of devices will be avoided, whilst keeping the existing models available until the end of the transition period.

The devices covered by a certificate issued under Directive 98/79/EC remain subject to ‘appropriate surveillance’ by the notified body that issued the certificate. Alternatively, the manufacturer can agree with a notified body designated under the IVDR that the latter becomes responsible for the surveillance. At the latest by the date when the written agreement between the manufacturer and the notified body for conformity assessment in accordance with the IVDR needs to be signed, that notified body would by default become responsible for the appropriate surveillance.

Article 3: entry into force

Article 3 provides for the entry into force of the Regulation on the date of its publication and a deferred application of the prior notice mechanism.

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

(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 Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Regulations (EU) 2017/745³ and (EU) 2017/746⁴ 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/EEC⁵ and 93/42/EEC⁶ and Directive 98/79/EC of the

¹ OJ C , , p. .

² OJ C , , p. .

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

⁴ 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>).

⁵ 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>).

⁶ 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>).

European Parliament and of the Council⁷, 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.

- (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 is significantly delayed, due to the technical complexity of 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 after the Commission has verified the full functionality of Eudamed and published a notice to that effect. The delayed development of the last electronic system therefore holds back the mandatory use of the 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 devices which are to undergo conformity assessment involving a notified body under that Regulation.
- (8) The number of applications for conformity assessment submitted by manufacturers and the number of certificates issued by notified bodies to date show that transition to the Regulation (EU) 2017/746 has not progressed in a way to ensure a smooth transition to the new rules.
- (9) It is very likely that many safe and critical *in vitro* diagnostic medical devices, which are essential for medical diagnosis and treatment of patients would not be certified in

⁷ 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>).

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 therefore 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 on notified bodies across time and 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 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 period.
- (13) To ensure a progressive transition to Regulation (EU) 2017/746, the appropriate surveillance regarding 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 medical devices concerned, so that the period is shorter for 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 may have on patient safety and public health, a prior notice mechanism should be introduced to enable in particular competent authorities and health institutions to take mitigating measures where necessary to ensure patient health and safety. Therefore, where manufacturers for any reason anticipate the interruption of supply of medical devices or *in vitro* diagnostic medical devices and it is reasonably foreseeable that the interruption may result in serious harm or a risk of serious harm to patients or public health in one or more Member States, the manufacturer should notify the relevant

competent authorities as well as the economic operators to whom they directly supply the device and, where applicable, the health institutions or healthcare professionals to whom they directly supply the device, thereof. The risk of serious harm to patients or public health may, for example, be due to the relevance of the device for ensuring essential healthcare services in one or more Member States, the dependency of patient health and safety on the continuous availability of the device in one or more Member States, or the absence of suitable alternatives, also considering the expected length of the supply interruption, the quantities of devices already made available on the market and available stocks or timelines for procuring alternative 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 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 Article 120 of Regulation (EU) 2017/745 and Article 110 of Regulation (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 the timely roll-out of Eudamed, 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. 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 last electronic system of Eudamed. In order to attain the intended effect of amending Regulations (EU) 2017/745 and (EU) 2017/746 and to ensure availability of devices whose certificates 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. 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.
- (18) To allow manufacturers and other economic operators time to adapt to the obligation to provide notice of an anticipated interruption of supply of certain devices, it is appropriate to defer the application of the provisions related to such 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 10a is inserted:

‘Article 10a

Obligations in case of interruption of supply of certain devices

1. Where a manufacturer anticipates an interruption of the supply of a device, other than a custom-made device, and where it is reasonably foreseeable that this interruption may 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 the manufacturer directly supplies the device, of the anticipated interruption.

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

2. The competent authority that has received the information referred to in paragraph 1 shall inform without undue delay the competent authorities of the other Member States and the Commission of the anticipated interruption.
3. The economic operators who have received the information from the manufacturer in accordance with paragraph 1, shall inform without undue delay any other economic operators, health institutions and healthcare professionals to whom they directly supply the device of the anticipated interruption.’

- (2) Article 34 is amended as follows:

- (a) in paragraph 1, the third sentence is deleted;
- (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 five years after 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 that date and at the earliest six months after the date of publication of the notice referred to in the first 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 13 is added:

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

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

- ‘- Articles 8 and 10, Article 10b(1), points (b) and (c), Article 10b(2) and (3) of Directive 90/385/EEC and 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;
- Article 10a, Article 10b(1), point (a), and Article 11(5) of Directive 90/385/EEC and 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), (c) and (d), respectively;’;

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

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

(i) in the first paragraph, the first sentence of 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 six months after 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).’;

(ii) after the twelfth indent, the following indent is inserted:

‘- Article 56(5),’;

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

‘- Article 78(1) to (13), without prejudice to Article 78(14),’;

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

‘Until the date of application of the provisions referred to in the first paragraph 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 6 months after the date referred to in point (d) of this paragraph, manufacturers shall ensure that the information to be entered in Eudamed in accordance with Article 29 is entered in the electronic system referred to in Article 33(2), point (a), also regarding the following devices, provided that the same devices are placed on market also from the date referred to in point (d) of this paragraph:
 - (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 after point (e):
 - ‘(ea) no later than 12 months after the date referred to in point (d) of this paragraph, notified bodies shall ensure that the information to be entered in Eudamed in accordance with Article 56(5) is entered in the electronic system referred to in Article 33(2), point (d), also regarding devices referred to in point (e), (i), of this paragraph. For those devices, only the latest relevant certificate and, if applicable, any decision taken by the notified body related to such certificate shall be entered;
 - (eb) by way of derogation from the first paragraph of point (d) 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 the first paragraph of point (d) of this paragraph, when a manufacturer has to submit a PSUR in accordance with Article 86(2) or report a serious incident, a field safety corrective action in accordance with Article 87 or submit a trend report in accordance with Article 88 through the electronic system referred to in Article 33(2), point (f), it shall also register the device, which is subject of the PSUR or the vigilance report, in the electronic system referred to in Article 33(2), point (a), except if such device was placed on the market in accordance with Directive 90/385/EEC or Directive 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 10a is inserted:

‘Article 10a

Obligations in case of interruption of supply of certain devices

1. Where a manufacturer anticipates an interruption of the supply of a device and where it is reasonably foreseeable that this interruption may 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.

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

2. The competent authority that has received the information referred to in paragraph 1 shall inform without undue delay the competent authorities of the other Member States and the Commission of the anticipated interruption.
3. The economic operators who have received the information from the manufacturer in accordance with paragraph 1, shall inform without undue delay any other economic operators, health institutions and healthcare professionals to whom they directly supply the device of the anticipated interruption.’

- (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 after 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 33(2), point (e), of that Regulation is functional and meets the functional specifications drawn up pursuant to Article 34(1) of that Regulation.

Before that date and at the earliest six months after the date of publication of the notice referred to in the first 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 afterwards shall 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 [OP: *please insert the date = 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 3a to 3e 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);
 - (ii) 26 May 2026, for devices referred to in paragraph 3b, point (b);
 - (iii) 26 May 2027, for devices referred to in paragraph 3b, point (c);
- (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 3b, point (a);
 - (ii) 26 September 2026, for devices referred to in paragraph 3b, point (b);
 - (iii) 26 September 2027, for devices referred to in paragraph 3b, point (c).
- 3d. By way of derogation from paragraph 3, 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 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 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 2025, the notified body that has signed the written agreement referred to in paragraph 3c, point (f), 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 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.’;

- (d) paragraph 8 is deleted;

- (e) the following paragraph 11 is added:
 - ‘11. Article 10a shall apply also to devices referred to in paragraphs 3, 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 (3e) and (4), 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, respectively, Article 33(2), points (e) and (f), of Regulation (EU) 2017/745;
 - (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, respectively, Article 33(2), points (a), (c) and (d), of Regulation (EU) 2017/745.’;
 - (b) the second paragraph is replaced by the following:

‘As regards the devices referred to in Article 110(3) to (3e) and (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 paragraph is amended as follows:
 - (1) the first sentence of the introductory wording is replaced by the following:

‘without prejudice to the obligations of the Commission pursuant to Article 34 of Regulation (EU) 2027/745, the obligations and requirements that relate to any of the electronic systems referred to in Article 33(2) of that Regulation shall apply from the date corresponding to six months after the date of publication of the notices referred to in Article 34(3) of that Regulation informing that the relevant electronic system is functional and meets the

functional specifications drawn up pursuant to Article 34(1) of that Regulation.’;

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

‘- 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 last indent is replaced by the following:

‘- Article 110(3d).’;

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

‘Until the date of application of the provisions referred to in the first paragraph 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 after point (f):

- ‘(fa) no later than 6 months after the date referred to in point (f) of this paragraph, manufacturers shall ensure that the information to be entered in Eudamed in accordance with Article 26 is entered in the the electronic system referred to in Article 33(2), point (a), of Regulation (EU) 2027/745 also regarding the following devices , provided that the same devices are placed on market also from the date referred to in point (f) 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 after the date referred to in point (f) of this paragraph, notified bodies shall ensure that the information to be entered in Eudamed in accordance with Article 51(5) of this Regulation is entered in the electronic system referred to in Article 33(2), point (d), of Regulation (EU) 2027/745 also regarding devices referred to in point (fa), (i), of this paragraph. For those devices, only the latest relevant certificate and, if applicable, any decision taken by the notified body related to such certificate shall be entered;
- (fc) by way of derogation from the first paragraph of point (f) of this paragraph, the obligations to upload the summary of safety and performance in accordance with Article 29(1) of this Regulation and to notify competent authorities in accordance with Article 50(1) of this Regulation, through the electronic system referred in Article 33(2), point (d), of Regulation (EU) 2017/745 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 the first paragraph of point (f) of this paragraph, when a manufacturer has to submit a PSUR in accordance with Article 81(2) or report a serious incident, a field safety corrective action in accordance with Article 82 or submit a trend report in accordance with Article 83 through the electronic system referred to in Article 33(2), point (f), of Regulation (EU) 2017/745, it shall also register the device, which is subject of the PSUR or the vigilance report, in the electronic system referred to in Article 33(2), point (a), of that 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 [*OP: please insert the date = 6 months after entry into force of this amending Regulation*].

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