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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices

Delegations will find attached document COM(2023) 10 final.

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EUROPEAN
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COM(2023) 10 final

2023/0005 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *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 (MDR)[1] and Regulation (EU) 2017/746 (IVDR)[2] of the European Parliament and of the Council establish a reinforced regulatory framework for medical devices and *in vitro* diagnostic medical devices. Their objectives are a high level of protection of health for patients and users and the smooth functioning of the internal market for these products. To achieve these objectives and, in light of issues identified with the previous regulatory framework, the Regulations set out a more robust system of conformity assessment to ensure the quality, safety, and performance of devices placed on the EU market.

The MDR has been applicable since 26 May 2021[3]. The transition period provided for in Article 120(3) will end on 26 May 2024.

The IVDR has been applicable since 26 May 2022. In January 2022, the European Parliament and the Council adopted a staggered extension of its transition period, ranging from 26 May 2025 for high risk *in vitro* diagnostics to 26 May 2027 for lower risk *in vitro* diagnostics, and to 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions[4].

Despite considerable progress over the past years, the overall capacity of conformity assessment ('notified') bodies remains insufficient to carry out the tasks required of them. In addition, many manufacturers are not sufficiently prepared to meet the strengthened requirements of the MDR by the end of the transition period. This is threatening the availability of medical devices on the EU market.

At present, 36 notified bodies are designated under Regulation (EU) 2017/745. Further 26 applications for designation as notified body are currently being processed; three of them are at an advanced stage[5].

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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).

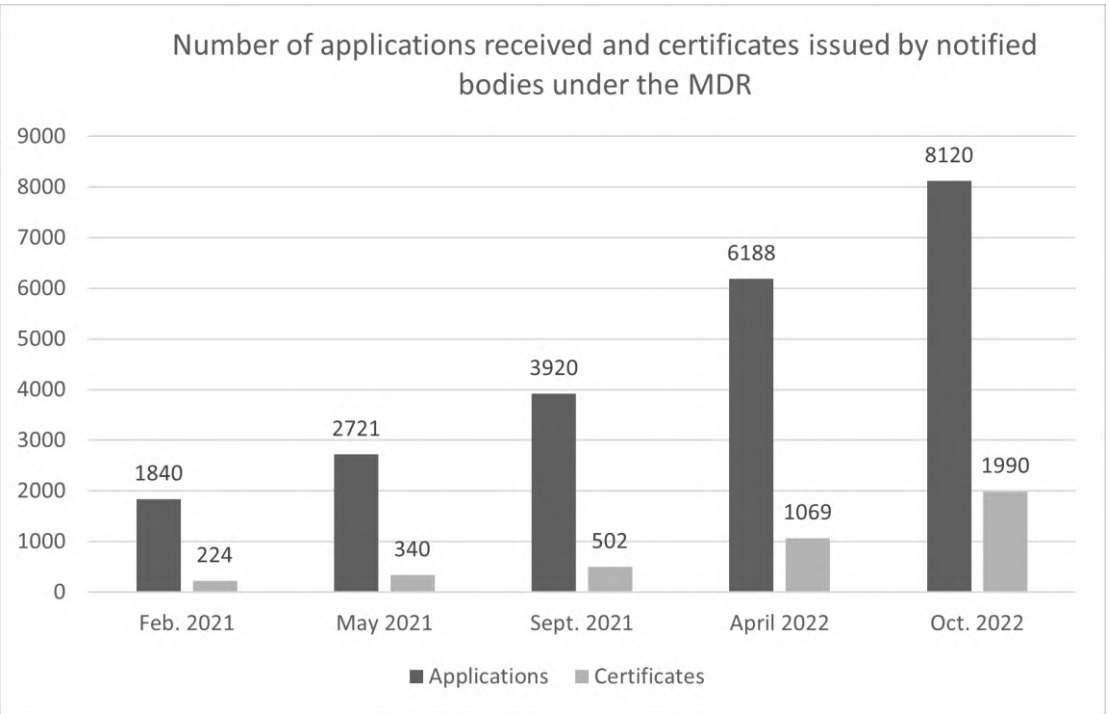
2 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

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) 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 9, 28.1.2022, p. 3).

5 In those three cases, the joint assessment team has already reviewed the applicants' corrective and preventive action plan. The length of the overall designation process varies considerably from case to case. Based on data from December 2021, the average length of the overall process was 842 days for a designation in accordance with the MDR.

In October 2022, notified bodies reported they had received altogether 8,120 applications from manufacturers for certification under the MDR and had issued 1,990 certificates in accordance with the MDR. According to an estimation presented by notified bodies to the Medical Device Coordination Group (MDCG)[6] on 17 November 2022, the number of certificates issued by May 2024 may reach around 7,000 if the current rate of certificate issuance remains the same with no changes to current conditions. Notified bodies estimate that the transition of all Directives' certificates to MDR certificates could possibly be completed by December 2027[7].



Source: European Commission, based on data provided by 30 notified bodies in October 2022.

This is in stark contrast to 21,376 valid certificates issued under Council Directive 90/385/EEC on active implantable medical devices (AIMDD)[8] and Council Directive 93/42/EEC on medical devices (MDD)[9] that will expire between January 2023 and 26 May 2024. Of those 21,376 certificates, 4,311 certificates will expire in 2023 and 17,095 certificates will expire in the first five months of 2024. Of note, 3,509 certificates issued under the AIMDD or MDD have already expired between May 2021 and December 2022.

6 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 is listed in the Commission's register of expert groups with the code X03565.

7 Based on the results of a survey among notified bodies conducted end of November/beginning of December 2022; the respondents represent notified bodies that have issued around 80% of all certificates issued under Council Directives 90/385/EEC and 93/42/EEC that were valid in October 2022. This estimation does not take into account the number of first MDR certification of devices for which no certificates have been issued under Council Directives 90/385/EEC and 93/42/EEC and which require notified body involvement under the MDR.

8 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).

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

Year of expiry	Number of expired/expiring certificates issued under Council Directives 90/385/EEC and 93/42/EEC
2021 (from 26 May)	1,139
2022	2,370
2023	4,311
2024 (until 26 May 2024)	17,095

Source: European Commission, based on data provided by notified bodies in 2021 and 2022.

After the expiry of the certificates issued under the Directives and without a valid MDR certificate, manufacturers are no longer allowed to place these medical devices on the EU market. This may cause shortages of medical devices, putting patient safety at risk. It is also likely to have a significant negative impact on innovation and business activity in the medical technology sector within the EU. The situation is exacerbated by the impact of the COVID-19 pandemic on clinical investigations, on-site audits and global supply chains, on which Russia's war of aggression against Ukraine is having a further negative impact.

The overall goal of the proposed amendments is to maintain patients' access to a wide range of medical devices while ensuring the transition to the new framework. The extension will be staggered depending on the risk class of the device, i.e. until December 2027 for devices with a higher risk and until December 2028 for medium and lower risk devices.

This proposal thus aims to extend the current transition period laid down in Article 120 of the MDR, based on certain conditions, so that only devices that are safe and for which manufacturers have already taken steps to transition to the MDR will benefit from the additional time. This would give manufacturers and notified bodies more time to conduct the conformity assessment procedures in accordance with the MDR, if those conditions are fulfilled. It also proposes to delete the 'sell-off' deadline in the relevant MDR and IVDR provisions, i.e. the end date for the further making available of devices which are placed on the market before or during the transition period and which are still in the supply chain when the extended transition period is over. This would prevent unnecessary disposal of safe medical devices that are already on the market but not yet with the final user.

The extension of the transition period is complemented by an extension of the validity of certificates issued under the previous Council Directives 90/385/EEC and 93/42/EEC for the devices benefiting from the extended transition period. Also the validity of certificates that have already expired since 26 May 2021 would be extended, subject to certain conditions.

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

The proposal is coherent with existing policy provisions as well as on-going non-legislative actions, which will complement the proposed amendment. On 25 August 2022, the MDCG endorsed its position paper MDCG 2022-14[10]. The paper lays out 19 non-legislative actions with a view to enhancing notified body capacity, access to notified bodies and manufacturers' preparedness and thereby support a successful transition to the MDR and IVDR. Several of the actions listed in MDCG 2022-14 have already been implemented, such as a MDCG position paper on hybrid audits[11], new MDCG guidance on appropriate surveillance[12], and a revision of MDCG 2019-6, removing obstacles to the employment of qualified personnel by notified bodies[13].

On 1 December 2022, the Commission adopted two delegated acts deferring the timing of the first complete re-assessment of notified bodies[14]. This is expected to free capacities both for designating authorities and notified bodies.

Work is ongoing to implement the remaining actions listed in MDCG 2022-14, as they remain important also if the transition period is extended.

Further actions to support implementation of the two Regulations are also (co-)funded under the 2022 and 2023 work programmes of the EU4Health Programme[15].

On 9 December 2022, the MDCG issued its position paper MDCG 2022-18[16] which sets out a uniform approach of competent authorities to applying market surveillance measures to bridge the gap between the expiry of MDD or AIMDD certificates and the issuance of MDR certificates. That approach is meant to be a temporary measure until the legislative changes in this proposal take effect. It contributes to avoiding

10 MDCG 2022-14 MDCG position paper Transition to the MDR and IVDR - Notified body capacity and availability of medical devices and IVDs (August 2022).

11 MDCG 2022-17 MDCG position paper on 'hybrid audits' (December 2022).

12 MDCG 2022-15 Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the 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 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD (December 2022).

13 MDCG 2019-6 Rev.4 Questions and answers: Requirements relating to notified bodies (October 2022).

14 Commission Delegated Regulation (EU) …/... of 1.12.2022 amending Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the frequency of complete re-assessments of notified bodies, C(2022) 8640, and Commission Delegated Regulation (EU) …/... of 1.12.2022 amending Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the frequency of complete re-assessments of notified bodies, C(2022) 8649. The delegated acts are available in the interinstitutional register of delegated acts and are subject to a three months scrutiny procedure by the European Parliament and the Council.

15 E.g. under the 2022 EU4Health Work Programme: a call for proposals aimed to foster capacity-building of existing and new notified bodies, to facilitate access of small and medium-sized enterprises (SMEs) and first-time applicants to notified bodies and to increase preparedness of manufacturers (see HS-g-22-19.03), various actions supporting the implementation of Regulations on medical devices and *in vitro* diagnostic medical devices (see HS-p-22-19.04, 06, 07, 08, 09, 10 and 11) and direct grants to Member States' authorities: reinforced market surveillance of medical devices and *in vitro* diagnostic medical devices (HS-g-22-19.01). Under the 2023 EU4Health Programme: support to the technical secretariat for Notified Bodies Coordination Group (see HS-p-23-63) and call for proposals for a program on orphan medical devices, in particular targeting paediatric patients (see HS-g-23-65).

16 MDCG 2022-18 MDCG position paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate.

disruption of supply of medical devices on the EU market. However, having regard to the number of certificates expiring in 2023 and 2024, it is not considered a sustainable solution for addressing the expected bottleneck of expiring certificates by 26 May 2024.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The proposal is based on Articles 114 and 168(4), point (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 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. In the case of the current proposal for an amendment, EU action is required to avoid disruption in the supply of devices across the EU, 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 avert the risk of shortages of medical devices across the EU. The proposed amendments aim to ensure that the intended purpose of the MDR and IVDR can be attained. That purpose is to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices, which guarantees a high level of protection of public health and patient safety and the smooth functioning of the internal market for these products. The proposal maintains the objective of both Regulations to ensure a high level of safety and performance of devices by enhancing their oversight by notified bodies. It only provides for the necessary additional time to achieve this objective. 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 devices may disappear from the market. Therefore, the proposed amendments to the MDR are limited to allowing a gradual phase-in of the requirements, limited to 'legacy' devices that need notified body involvement in the conformity assessment, without altering the substance of those requirements, and the deletion of the 'sell-off' deadline. The amendment of the IVDR is limited to the deletion of the 'sell-off' deadline in order to be consistent with the proposed change in the MDR. The Commission proposes to differentiate between higher risk devices (i.e. class III and class IIb implantable) and lower risk devices (i.e. other class IIb, class IIa and class Im, Is, Ir[17]), with shorter transition periods for higher risk devices and longer periods for lower risk ones. This approach aims to balance the available

[17] Class Im means class I devices with a measuring function; class Is means class I devices that are placed on the market in sterile condition; class Ir means class I devices that are reusable surgical instruments.

notified body capacity and the level of manufacturers' preparedness with high level of public health protection.

- **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

Given the urgent nature of this proposal, 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, allowing for additional time to transition to the MDR's requirements to avoid shortages. The need to act quickly to ensure certainty ahead of the Regulation's current end of transition period did not allow for a broad public consultation. The Commission therefore collected the necessary input from Member States and stakeholders through targeted exchanges.

The initiative aims to assure that patients throughout Europe have access to safe medical devices. As more and more certificates will expire before the May 2024 deadline, the Commission has committed to adopt a proposal in January 2023. This is backed up by urgent calls from the European Parliament, Member States and stakeholders, namely healthcare professionals, patients, academia, scientific bodies, industry and notified bodies. Input from Member States and stakeholders has been sought through targeted interaction, mainly in the framework of the Medical Device Coordination Group (MDCG) with meetings on 24-25 August, 24-25 October and 17 November 2022, dedicated to capacity and preparedness issues. Following a debate in the European Parliament on 24 November 2022 (oral question O-43/2022), the European Parliament's Committee on Environment, Public Health and Food Safety requested an urgent targeted amendment in a letter of 5 December 2022. An exchange of views with Member States took place on 9 December 2022 during the EPSCO Health Council[18]; almost all Member States took the floor and supported the urgent adoption of a targeted amendment of the MDR and IVDR as suggested by the Commission.

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.

[18] See Commission information note circulated as Council document 15520/22 of 6.12.2022.

5. OTHER ELEMENTS

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

  Article 1 contains the proposed amendments to Article 120(2), (3) and (4) and to Articles 122 and 123 of the MDR. Article 2 contains the amendments to Article 110(4) and to Article 112 of the IVDR.

- **Article 1(1), point (a), of the proposal – extension of the validity of certificates**

  This provision amends Article 120(2) MDR. It extends the validity of certificates issued under Council Directives 90/385/EEC or 93/42/EEC that were valid on the day of the MDR's date of application (26 May 2021) 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 transition period laid down in the proposed Article 120(3a) to (3c) of the MDR. As regards certificates that have already expired when the proposed amendment comes into force, the extension would 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 59 of the MDR or have required the manufacturer to carry out the conformity assessment procedure within a specific time period in accordance with Article 97 of the MDR.

- **Article 1(1), point (b), of the proposal – extension of the transition period**

  This provision amends Article 120(3) MDR. Due to the length of the provision, paragraph 3 is replaced by paragraphs 3a to 3g. The transition period is extended from 26 May 2024 until 31 December 2027 for higher risk devices (class III and class IIb implantable devices except certain devices for which the MDR provides exemptions, given that these devices are considered to be based on well established technologies) and until 31 December 2028 for medium and lower risk devices (other class IIb devices and class IIa, class Im, Is and Ir devices).

  In the same way as the current Article 120(3) MDR, the extended transition period applies only to 'legacy devices', i.e. those covered by a certificate or declaration of conformity issued under Council Directives 90/385/EEC or 93/42/EEC before 26 May 2021.

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

  - the devices must continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable. This condition is already part of the current Article 120(3) MDR;

  - the devices do not undergo significant changes in the design and intended purpose. This condition is already part of the current Article 120(3) MDR;

- 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 94 and 95 of the MDR. No systematic check of the device's safety is required, as devices covered by a certificate issued under the Directives will be under 'appropriate surveillance' by the body that issued the certificate or a notified body designated under the MDR. 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 2024, the manufacturer has put in place a quality management system (QMS) in accordance with Article 10(9) of the MDR. This condition aims to ensure that manufacturers gradually move towards full compliance with the MDR 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. However, by submitting an application for conformity assessment to a notified body (see next condition), the manufacturer implicitly confirms that its QMS is in compliance with the MDR;

- no later than 26 May 2024, the manufacturer, or its authorised representative, has lodged a formal application in accordance with Annex VII, Section 4.3, of the MDR for conformity assessment in respect of a '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 MDR, and no later than 26 September 2024 the notified body and the manufacturer have signed a written agreement in accordance with Annex VII, Section 4.3, of this Regulation. This condition aims to ensure that only devices that the manufacturer intends to transition to the MDR 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 26 May 2024. 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, whist keeping the existing models available until the end of the transition period.

The devices covered by a certificate issued under the AIMDD or MDD 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 MDR 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 MDR needs to be signed, that notified body would by default become responsible for the appropriate surveillance.

The amendment introduces a transition period until 26 May 2026 also for class III custom-made implantable devices, which are currently not covered by Article 120(3) MDR. While manufacturers of class III implantable custom-made devices are required to comply with all applicable MDR requirements since 26 May 2021, they will now be given more time to obtain certification of their quality management system by a notified body. Also in this case, the transition period only applies if the

manufacturer has lodged an application before 26 May 2024 resulting in the signing of a contract with the notified body before 26 September 2024.

- **Article 1(1), point (c), of the proposal – deletion of the 'sell-off' deadline in the MDR**

  This provision deletes the current 'sell-off' date (27 May 2025) in Article 120(4) MDR. Consequently, devices placed on the market before the end of the transition period can be made further available on the market without a legal time restriction.

- **Article 1(2) and (3) of the proposal – adaptation of Articles 122 and 123 MDR**

  This provision adapts Articles 122 and 123 MDR to reflect the extended transition period and the deletion of the 'sell-off' deadline.

- **Article 2(1) of the proposal – deletion of the 'sell-off' deadlines in the IVDR**

  This provision deletes the current 'sell-off' dates (25 May 2025 to 26 May 2028) in Article 110(4) IVDR. Consequently, devices placed on the market before the end of the transition period laid down in Article 110(3) IVDR can be made further available on the market without a legal time restriction.

- **Article 2(2) of the proposal – adaptation of Article 112 IVDR**

  This provision adapts Article 112 IVDR to reflect the deletion of the 'sell-off' deadlines.

2023/0005 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *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,

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) Regulations (EU) 2017/745[1] and (EU) 2017/746[2] of the European Parliament and of the Council establish a new 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 in Council Directives 90/385/EEC[3] and 93/42/EEC[4] and Directive 98/79/EC of the European

[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] 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).

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

Parliament and of the Council[5], such as the supervision of notified bodies, conformity assessment procedures, clinical evidence requirements, vigilance and market surveillance, whilst introducing provisions ensuring transparency and traceability regarding medical devices and *in vitro* diagnostic medical devices.

(2) Due to the impact of the COVID-19 pandemic, the date of application of Regulation (EU) 2017/745 has been postponed by one year to 26 May 2021 by Regulation (EU) 2020/561 of the European Parliament and of the Council[6], while the date of 26 May 2024 was maintained as end of the transition period by which certain devices that continue to comply with Directive 90/385/EEC or Directive 93/42/EEC may be placed on the market or put into service.

(3) Also due to the impact of the COVID-19 pandemic, the transition period provided for in Regulation (EU) 2017/746 has already been extended by Regulation (EU) 2022/112 of the European Parliament and of the Council[7].

(4) Despite the steady increase in the number of notified bodies designated in accordance with Regulation (EU) 2017/745, the overall capacity of notified bodies is still not sufficient to ensure the conformity assessment of the large number of devices covered by certificates issued under Directive 90/385/EEC or Directive 93/42/EEC before 26 May 2024. It appears that a large number of manufacturers, especially small and medium-sized enterprises, are not sufficiently prepared to demonstrate compliance with the requirements of Regulation (EU) 2017/745, taking into account also the complexity of those new requirements. Therefore, it is very likely that many devices that may be placed on the market in accordance with the transitional provisions provided for in Regulation (EU) 2017/745 are not going to be certified in accordance with that Regulation before the end of the transition period, which leads to the risk of shortages of medical devices in the Union.

(5) In light of reports from healthcare professionals about the imminent risk of shortages of devices, it is necessary, as a matter of urgency, to extend the validity of certificates issued under Directives 90/385/EEC and 93/42/EEC and to extend the transition period during which devices that are in conformity with those Directives can be placed on the market. The extension should be sufficiently long to give notified bodies the time needed to carry out the conformity assessments required of them. The extension aims at ensuring a high level of public health protection, including patient safety and an avoidance of shortages of medical devices needed for the smooth functioning of health services, without lowering current quality and safety requirements.

(6) The extension should be subject to certain conditions to ensure that only devices that are safe and for which the manufacturers have taken steps to transition towards compliance with Regulation (EU) 2017/745 will benefit from the additional time.

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5 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).

6 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).

7 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).

(7) To ensure progressive transition to Regulation (EU) 2017/745, the appropriate surveillance regarding devices benefiting from the transition period should eventually pass over from the body that has issued the certificate in accordance with Directive 90/385/EEC or Directive 93/42/EEC to a notified body designated under Regulation (EU) 2017/745. For reasons of legal certainty it should be provided that the notified body should not be responsible for conformity assessment and surveillance activities carried out by the outgoing body.

(8) As regards the period of time needed to allow manufacturers and notified bodies to carry out the conformity assessment in accordance with Regulation (EU) 2017/745 of medical devices that had been CE marked in accordance with Directive 90/385/EEC or Directive 93/42/EEC, 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 transition 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.

(9) Contrary to Directives 90/385/EEC and 93/42/EEC, Regulation (EU) 2017/745 requires the involvement of a notified body in the conformity assessment of class III custom-made implantable devices. Having regard to insufficient notified body capacity and the fact that manufacturers of custom-made devices are often small or medium-sized enterprises that did not have access to a notified body under Directives 90/385/EEC and 93/42/EEC, a transition period should be provided during which class III custom-made implantable devices may be placed on the market or put into service without a certificate issued by a notified body.

(10) Article 120(4) of Regulation (EU) 2017/745 and Article 110(4) of Regulation (EU) 2017/746 prohibit the further making available of devices which are placed on the market by the end of the applicable transition period and which are still in the supply chain one year after the end of that transition period. To prevent unnecessary disposal of safe medical devices and *in vitro* diagnostic medical devices that are still in the supply chain, thus adding to the imminent risk of shortages of devices, such further making available of devices should be unlimited in time.

(11) The adoption of this Regulation takes place due to exceptional circumstances arising from an imminent risk of shortages of medical devices and the associated risk of a public health crisis. In order to attain the intended effect of the amendments to 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 2024, to provide legal certainty for economic operators and healthcare providers, and for reasons of consistency as regards the amendments to both Regulations, it is necessary for this Regulation to enter into force as soon as possible. For the same reasons it is also 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 Treaty on European Union, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community,

HAVE ADOPTED THIS REGULATION:

Article 1

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

(1) Article 120 is amended as follows:

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

'Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC as from 25 May 2017 that were valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the dates set out in paragraph 3b for the relevant risk class of the devices. Certificates referred to in the first sentence that have expired before [*OP please insert the date – date of entry into force of this Regulation*] shall be considered to be valid until the dates set out in paragraph 3b 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 for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device;

(b) a competent authority of a Member State has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) or has required the manufacturer, in accordance with Article 97(1), to carry out the applicable conformity assessment procedure';

(b) paragraph 3 is replaced by the following:

'3a. By way of derogation from Article 5 and provided the conditions set out in paragraph 3d of this Article are met, devices referred to in paragraphs 3b and 3c of this Article may be placed on the market or put into service until the dates set out in those paragraphs.

3b. Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:

(a) 31 December 2027, for class III devices and for class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;

(b) 31 December 2028, for class IIb devices other than those covered by point (a), for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

3c. Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until 31 December 2028.

3d. Devices may be placed on the market or put into service until the dates referred to in paragraphs 3b and 3c of this Article only if the following conditions are met:

(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

(b) there are no significant changes in the design and intended purpose;

(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);

(e) no later than 26 May 2024, the manufacturer, or an authorised representative, has lodged a formal application in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraphs 3b and 3c of this Article or in respect of a device intended to substitute that device, and no later than 26 September 2024 the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

3e. By way of derogation from paragraph 3a, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to devices referred to in paragraphs 3b and 3c of this Article in place of the corresponding requirements in Directives 90/385/EEC and 93/42/EEC.

3f. Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in paragraph 3b of this Article shall continue to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices it has certified, unless the manufacturer has agreed with a notified body designated in accordance with Article 42 that the latter shall carry out that surveillance.

No later than 26 September 2024, the notified body that has signed the written agreement referred to in paragraph 3d, point (e), shall be responsible for the surveillance in respect of the devices covered by the written agreement. Where the written agreement covers a device intended to substitute a device which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC, the surveillance shall be conducted in respect of the device that is being substituted.

The arrangements for the transfer of the surveillance from the notified body that issued the certificate to the notified body designated in accordance with Article 42 shall be defined in an agreement between the manufacturer, 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.

3g. By way of derogation from Article 5, class III custom-made implantable devices may be placed on the market or put into service until 26 May 2026 without a certificate issued by a notified body in accordance with the conformity assessment procedure referred to in Article 52(8), second subparagraph, provided that no later than 26 May 2024, the manufacturer, or the authorised representative of the manufacturer, has lodged a formal application in accordance with Section 4.3, first subparagraph, of Annex VII for the applicable conformity assessment, and no later than 26 September 2024 the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.';

(c) paragraph 4 is replaced by the following:

'4. Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices placed on the market from 26 May 2021 pursuant to paragraphs 3a, 3b, 3c and 3g of this Article, may continue to be made available on the market or put into service.'

(2) Article 122 is amended as follows:

(1) in the first paragraph, the introductory wording is replaced by the following:

'Without prejudice to Article 120(3a) to (3f) and (4) of this Regulation, and without prejudice to the obligations of the Member States and manufacturers as regards vigilance and to the obligations of manufacturers as regards the making available of documentation, under Directives 90/385/EEC and 93/42/EEC, those Directives are repealed with effect from 26 May 2021, with the exception of:';

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

'As regards the devices referred to in Article 120(3a) to (3f) and (4) of this Regulation, the Directives referred to in the first paragraph shall continue to apply to the extent necessary for the application of those paragraphs.';

(3) In Article 123(3), point (d), the twenty-fourth indent is replaced by the following:

'- Article 120(3e).'.

Article 2

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

(1) in Article 110, paragraph 4 is replaced by the following:

‘4. Devices lawfully placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022, and 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.’;

(2) in Article 112, the second paragraph is replaced by the following:

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

Article 3

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	*For the Council*
The President	*The President*