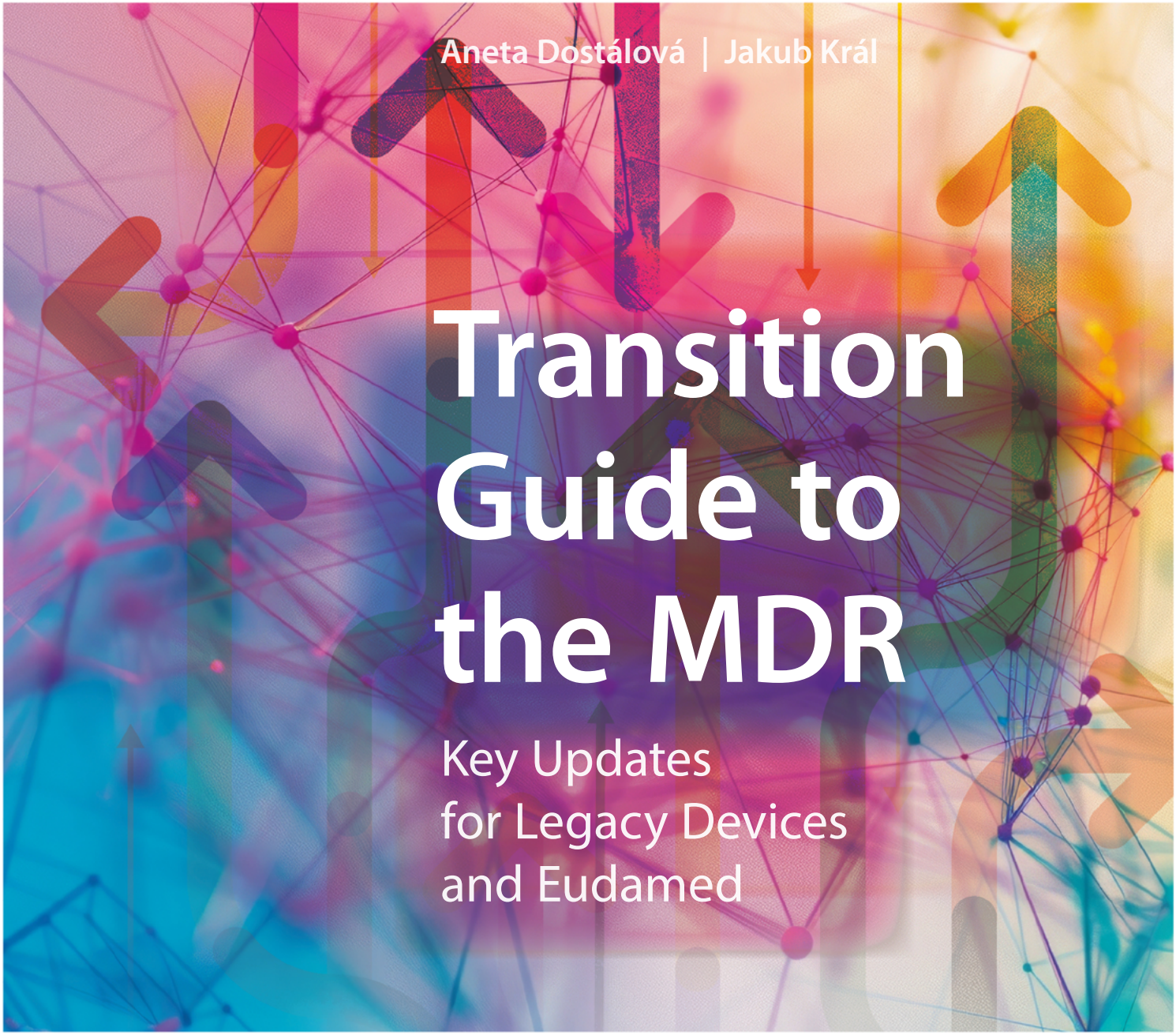

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Transition Guide to the MDR
Key Updates for Legacy Devices and Eudamed

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Transition Guide to the MDR

Key Updates for Legacy Devices and Eudamed

Introduction

The purpose of this publication is to provide readers with an overview of the key changes brought about by Regulation (EU) 2023/607 in the field of medical devices and to present its real impact on the obligations of all stakeholders. This is an amendment to Regulation (EU) 2017/745 that has a major impact on the immediate future of many medical devices. In fact, it allows, subject to certain conditions, for several more years to place devices with conformity assessed under the previously applicable law on the market, although the legislator's original intention was to limit this possibility to May 2024 at the latest.

The second part of this practical guide provides an overview of the changes concerning the use of the European Medical Device Database Eudamed. Regulation 2024/1860 aims to allow the mandatory use of the individual already functional modules of the database without waiting for its complete finalisation.

The two amending regulations share a common objective: to correct the wrong estimation of future developments by the authors of Regulation (EU) 2017/745. For medical devices with conformity assessed under the previously applicable rules, recertification under the new rules has proven to be more complex and slower than originally anticipated. On the contrary, in the case of the Eudamed database, it was found that its use for individual areas needs to be enabled before the database is ready as a whole.

I hope that this guide will provide you with greater clarity on both topics and help you to better navigate the complex text of the two amending regulations. The publication is part of a wider range of educational activities of the Czech Standardization Agency, which are aimed primarily at domestic suppliers of medical devices.

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Extension of transitional periods for legacy devices

The Medical Devices Regulation (EU) 2017/745 (**MDR**) introduced a strengthened regulatory framework for medical devices in 2017. The existing, albeit harmonised, legislation in the form of the Directives[1] has proven to be insufficient and does not provide the proper level of protection for the health of patients and users and the smooth functioning of the single market for these types of products. The Regulation has therefore brought about a more sophisticated and detailed system of conformity assessment of devices, with an emphasis on their quality, safety and efficacy and a responsible approach of the economic operators involved.

As with the adoption of any other legislation that fundamentally interferes with the very essence of rules, the implementation of the MDR required the resolution of the timing and content of the transition to the new rules, i.e., clearly defining what will happen to existing medical devices that have been assessed for compliance under the existing legislation (**legacy devices**), and whether, under what conditions, and for how long after the MDR is fully applicable (26 May 2021) they will be allowed to be traded, i.e. placed on the market by the manufacturer or supplied within the distribution chain.

Legacy devices must be distinguished from medical devices whose conformity has also been assessed under the existing directives, but which – unlike legacy devices – were placed on the market before the MDR itself came into force (**old devices**) and are therefore in a mere sell-off mode after its entry into force.

In order for a medical device to benefit from the legacy devices' regime, certain conditions had to be met. It had to be a medical device of a higher[2] risk class; medical devices of risk class I, for which the conformity assessment process either under the previous directives or under the MDR did not require the involvement of a notified body, were not covered by any transitional provision and had to be brought into conformity with the MDR by the date of its applicability. Furthermore, the conditions had to be met that the 'old' certificate had not yet expired, the devices continued to comply with one of the directives and there were no significant changes in their design or intended purpose.

Regarding the timeframe, the original MDR foresaw that legacy devices could be placed on the market until 26 May 2024. The deadline for their sell-off within the distribution chain was even one year longer, so they could be made available on the market or put into service until 26 May 2025.

At the time of the adoption of the MDR (5 April 2017), the length of such a transitional period, reinforced by the long legalisation period, seemed sufficient for manufacturers, other economic operators, as well as notified bodies

1 Council Directive 93/42/EEC, on medical devices (**MDD**), and 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 (**AIMDD**).

2 Medical devices of risk classes IIa, IIb, III and up-classified medical devices for which the conformity assessment procedure under the Directives did not require the involvement of a notified body but for which the conformity assessment procedure under the MDR already requires the involvement of a notified body.

involved in the conformity assessment of medical devices to adapt to the rules of the new regulation both substantively and organisationally. However, over time it became clear that this estimate did not correspond to reality.

Reasons for the adoption of EU Regulation 2023/607

Although manufacturers and other stakeholders had 4 years[3] to familiarise themselves with the new obligations and to plan for a gradual transition to the new rules, for which an additional three-year period was also provided in the form of a transitional provision in Article 120 MDR until May 2024, it became clear by 2022, at the latest, that even this generous period was not sufficient to allow a smooth recertification of approximately 20,000 devices[4]. This was not only due to the unpreparedness of manufacturers caused by the COVID-19 pandemic and other events of the early 2020s, such as the war in Ukraine, rising energy costs and inflation, but also to the capacity of the notified bodies, which proved to be completely inadequate. By no means all notified bodies that had assessed compliance under previous directives were able to secure timely appointments to assess compliance under the MDR.

There was a real risk that a number of legacy devices would not be MDR certified by 26 May 2024, leading to a shortage of some medical devices on the European market. Therefore, the Health Ministers at the EPSCO Council called on the Medical Devices Coordination Group (MDCG) to urgently propose[5] the necessary steps to eliminate the risk of a major unavailability of medical devices on the EU market.

MDCG has introduced a total of 19 non-legislative measures[6]. Additional MDCG papers were published in the second half of 2022 in an effort to recommend approaches to address the situation[7].

3 The original three-year legislative deadline has been extended by an additional year due to the COVID-19 epidemic, so the applicability of the MDR has moved from 26 May 2020 to 26 May 2021.

4 MEDTECH EUROPE. Analysing the availability of medical devices in 2022 in connection to the medical device regulation (MDR) implementation [online]. July 2022 [cited 2024-06-07]. Available from: https://www.medtecheurope.org/wp-content/uploads/2022/07/medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-mdr-implementation.pdf
EUROPEAN PARLIAMENT. Oral questions O-000014/2022 [online]. 2022 [cited 2024-06-07]. Available from: https://www.europarl.europa.eu/doceo/document/O-9-2022-000014_CS.html.

5 MEDTECH EUROPE. EPSCO Council meeting on 14 June 2022 [online]. 2022 [cit. 2024-06-07]. Available from: https://www.medtecheurope.org/news-and-events/news/epsco-council-meeting-on-14-june-2022/.

6 MDCG 2022-4 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.

7 E.g. MDCG 2022-17 MDCG position paper on "hybrid audits" or MDCG 2019-6 Questions and answers: Requirements relating to notified bodies.

Unfortunately, in the meantime, non-legislative measures have proven to be insufficient to avert the impending risk.[8] In October 2022, the European Commission published the results of a survey of notified bodies on the status of certification and review requests under the MDR[9]. The source of the information was the most relevant bodies, namely the notified bodies appointed for conformity assessment under the MDR. The survey revealed that there was a risk of unavailability of some key medical devices both in healthcare facilities and to patients. It also predicted a significant slowdown in the entry of innovative medical devices into the EU market.

The only other possible solution that would be truly effective was a legislative change to the MDR itself. Therefore, on 6 January 2023, the European Commission adopted a proposal to extend the transition period for the re-certification of legacy devices. Once approved, the proposal was published on 20 March 2023 in the Official Journal as Regulation (EU) 2023/607 (**Regulation 2023/607**).

New transitional periods after the adoption of Regulation 2023/607

The new transitional provisions of the MDR, following the adoption of Regulation 2023/607, are similar in content to the former transitional provisions. Specifically, they address:

- which certificates are affected by the transitional provisions;
- until when they are extended or renewed in cases where they have expired, and what conditions must be met for the extension or renewal of certificates;
- for how long devices with such certificates may be placed on the market and what other conditions must be met for their placing on the market;
- for how long legacy devices can be traded in the distribution chain;
- which MDR provisions apply to legacy devices and which do not;
- what about the surveillance of legacy devices by notified bodies;
- what rules apply to up-classified devices;
- the parallel placing on the market of legacy devices and the devices that replace them after MDR certification.

In general, in order for a legacy device to continue to be placed on the market and benefit from extended transitional periods, it must meet two conditions. That is, (1) there must be a **valid certificate**, or a renewed one if it has expired, and (2) the prescribed **requirements for placing on the market must** be met. These two conditions, each of which has an additional level of specific conditions of its own, need to be distinguished, although they are closely interrelated. Simply put, a valid or renewed certificate does not mean that a legacy device can be placed on the market without further delay or conditions.

Affected certificates

The certificates covered by the transitional provision of Article 120(2) MDR as amended by Regulation 2023/607 include all certificates that were normally issued by

8 See: JAROSCHYOVÁ, Aneta. The Commission wants to extend the end of the MDR implementation transition period, but only for ready manufacturers [online]. Porta Medica, 14 December 2022 [cited 2024-06-05]. Available from: https://www.portamedica.eu/post/commission-wants-to-extend-the-end-of-the-mdr-implementation-transition-period-but-only-for-ready-m.

9 Notified bodies survey on certifications and applications available at https://health.ec.europa.eu/latest-updates/updated-document-notified-bodies-survey-certifications-and-applications-mdrivdr-survey-results-data-2023-07-25_en.

notified bodies with reference to the previous directives (MDD and AIMDD), i.e.:

- EC Design Examination Certificate (Annex II, Section 4 MDD; Annex 2, Section 4 AIMDD),
- EC Certificate of Conformity (Annex IV MDD, Annex 4 AIMD),
- EC Type Examination certificate (Annex III MDD, Annex 3 AIMD),
- EC Certificate Full Quality Assurance System (Annex II excluding section 4 of MDD; Annex 2, section 2 AIMD),
- EC Certificate Production Quality Assurance (Annex V MDD, Annex 5 AIMD),
- EC Certificate Product Quality Assurance System (Annex VI MDD)[10].

The new transitional provision divides the certificates into two groups and sets different conditions for the extension of their validity for each group. The following chapter discusses it in detail.

Extension of certificates

Certificates issued before 25 May 2017

According to both the former transitional provisions and the new transitional provisions under Regulation 2023/607, legacy device certificates issued in accordance with previous MDD and AIMDD directives **prior to 25 May 2017** remain valid until the end of the validity period indicated on the certificate, except for certificates issued in accordance with Annex 4 AIMDD or Annex IV MDD, which expire no later than 27 May 2022. These certificates are therefore unaffected by the issuance of Regulation 2023/607 and nothing changes for them.

Certificates issued after 25 May 2017

According to the original MDR, legacy device certificates issued in accordance with the previous MDD and AIMDD after **25 May 2017** remained valid until the expiration date stated on the certificate, but no later than 26 May 2024. Regulation 2023/607 brought a fundamental change.

Regulation 2023/607 established extended validity dates for legacy device certificates issued in accordance with previous MDD and AIMDD after May 25, 2017. This was done on the basis of their belonging to risk classes:

- For all Class III devices and Class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the deadline is **31 December 2027**.

  It is important to note that the 31 December 2027 deadline applies to all Class III devices and only to certain Class IIb implantable devices with the exceptions noted. This is therefore not the same set of exemptions as set out in Article 61 MDR for the mandatory clinical trial, where the exemptions listed (suture materials and others) apply to both Class IIb and Class III. In other words, for sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, if they are Class III risk, the date of 31 December 2027 applies in the context of this transitional provision; however, if they are Class IIb implantable, the date of 31 December 2028 applies.

- For other devices, i.e. non-implantable Class IIb devices, implantable Class IIb devices in the case of suture materials staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips

10 CAMD. Transition Sub Group: Frequently Asked Questions – Transitional Provisions to the MDR, Question 9 [online] CAMD [cited 2024-06-05]. Available from: https://www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_180117_V1.0-1.pdf.

and connectors, Class IIa devices and Class I devices sterile or with a measuring function, the deadline is **31 December 2028**.

We want to emphasise that for the determination of the end of the transition period (31 December 2027 or 31 December 2028), the MDD classification is not decisive, but the risk class determined according to the classification rules set out in Annex VIII MDR[11] applies.

Certificates that did not expire before 20 March 2023 have no further conditions and are valid until 31 December 2027 or 31 December 2028 without further notice.

Certificates that expired before 20 March 2023 must already meet certain conditions to remain valid until 31 December 2027 or 31 December 2028. At this point, we consider it appropriate to stress that in such cases, it is de facto a "renewal" of the validity of the certificates, not an "extension" of their validity period, since what has once expired cannot be extended, but only renewed. The conditions for renewal of such certificates are as follows:

- before the expiry date of the certificate, the manufacturer and the notified body had signed a written conformity assessment agreement in accordance with the second paragraph of Section 4.3 of Annex VII MDR in respect of the device covered by the expired certificate or in respect of the device intended to substitute that device, in other words the manufacturer has already started the re-certification process but has not yet completed it,

or

- the manufacturer has received a national derogation under Article 59(1) MDR or Article 97(1) MDR.

The first derogation is granted by the competent Member State which, on the basis of a reasoned request, has authorised the placing on the market or putting into service in its territory of a specific device for which the mandatory procedures have not been carried out but whose use is in the interest of protecting public health or the safety or health of patients. Article 59 MDR makes it clear that the general derogation to allow the placing on the market or putting into service of a device for which no conformity assessment has been carried out applies only to the territory of the Member State concerned. However, if an expired certificate of conformity issued under the MDD or the AIMDD is renewed as a result of the derogation under Article 59 MDR, the renewed certificate is valid throughout the EU. Thus, the legacy devices concerned can be legally placed on the market on the basis of the certificate, but only if all other necessary conditions are also met.

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The second derogation represents a situation where the competent authority of the Member State concerned has identified a non-compliance of a device with the requirements of the MDR, but because the device or its non-compliance does not present an unacceptable risk to the health or safety of patients, users or other persons, it has set a deadline for the economic operator to remedy the non-compliance.

Please note that this transitional provision of the MDR does not take into account the situation where the derogation under Article 59(1) MDR is limited in time or where the economic operator fails to remedy the non-compliance within a specified period of time. The Commission commented in its informal opinion[12] that such devices are subject to the full extended transitional period (i.e. until 31 December 2027 or 31 December 2028) as long as the conditions for their placing on the market are met and the certificate is considered valid until the end of the relevant transitional period, unless it is withdrawn.

With validity extension of the legacy device certificates, a practical question has arisen as to how the manufacturer, or other links in the supply chain, should demonstrate compliance with the conditions for the extension of the transitional period (e.g. when supplying a device to a third country or participating in a public procurement procedure). According to the MDCG 2020-3[13], notified bodies cannot issue new MDD/AIMDD certificates during the transition period. For these purposes, a written declaration from the manufacturer or a confirmation letter from the notified body should be used, and harmonised templates of these documents have been published at EU level[14]. As regards the evidence of the fact that the procedure under Article 97 MDR has been applied to the device, it is necessary to submit a decision of the competent authority on this procedure, which temporarily replaces the missing certificate of conformity and declaration of conformity.

Rules for making the device available on the market

As mentioned in the introduction, the extension or renewal of a certificate does not mean that the medical device can be placed on the EU market without further delay or conditions. Regulation 2023/607 sets out the deadlines for making available on the market or putting into service and the conditions that must be met.

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13 MDCG 2020-3 Rev.1 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.

14 A template for the manufacturer's declaration in the context of Regulation (EU) 2023/607 is available at: https://www.medtecheurope.org/resource-library/manufacturers-declaration-in-relation-to-regulation-eu-2023-607/ and a template for the notified body's confirmation of the status of the formal application, written agreement and corresponding surveillance in the sense of Regulation (EU) 2023/607 is available at: https://health.ec.europa.eu/medical-devices-dialogue-between-interested-parties/overview_en.

Dates for placing legacy devices on the market

The dates vary depending on the risk class of the device:

- for Class III devices and Class IIb implantable devices, excluding suture materials, clips and staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the date shall be **31 December 2027**;
- for other devices, i.e. non-implantable Class IIb devices, implantable Class IIb devices in the case of suture materials, clips and staples, dental fillings, dental braces, tooth crowns, screws, rings, plates, wires, pins, clips and connectors, Class IIa devices and Class I devices sterile or with a measuring function, the date shall be **31 December 2028**.

Conditions for placing legacy devices on the market

In addition to being a device with a valid or renewed certificate, certain conditions have to be met in order to apply these transitional periods:

The first two are the same as in the original MDR version:

1. the devices must continue to comply with MDD or AIMDD, and
2. there must be no significant changes in the design and intended purpose of the product.

The other three conditions are newly established:

3. the devices must not pose an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of public health protection,
4. implementation of a quality management system (**QMS**) according to Article 10(9) MDR by 26 May 2024; and
5. submission of a formal application for MDR conformity assessment to a notified body by 26 May 2024 and signing of a written re-certification agreement with the notified body by 26 September 2024.

On the condition of compliance with MDD or AIMDD
Devices that did not comply with the original directives or that have lost compliance over time cannot be made available on the market as legacy devices. Compliance with the conformity requirements for certified devices also means that they continue to be under the surveillance by the original notified body up to and including 25 September 2024, unless the manufacturer agrees the surveillance with a new notified body.

On the condition prohibiting significant changes
The conditions for placing legacy devices on the market or putting into service require that no significant changes are made to the design or intended purpose of the device after the MDR mandatory applicability date of 26 May 2021. It is therefore important that manufacturers and notified bodies clarify what changes to the device will be considered significant and capable of affecting the validity of the certificate issued.

In this context, we stress that the issue of new certificates under the regime of previous directives, including modified, amended or supplemented certificates, is not allowed. In particular, if a manufacturer wishes to make a 'significant change to the design or intended purpose', making such a change would prevent the manufacturer from continuing to place the device on the market or put into service under the legacy devices' regime.

Changes and their implementation should be subject to verification by the notified body in the framework of surveillance activities or following a manufacturer's request for prior approval. The outcome of this verification will determine whether the certificate issued under the regime of the previous Directives remains valid.

The notified body that issued the certificate may, after reviewing the manufacturer's proposed description of the change, confirm in writing that the change does not constitute a significant change to the design or intended purpose and that the subject certificate remains valid beyond the mandatory applicability date of the MDR, but no later than 31 December 2027 or 31 December 2028. Such written confirmation corrects or supplements the information in the certificate, but does not constitute the issuance of an ‚amended certificate' as this is prohibited. In case of an inspection by the competent authorities, the manufacturer should number such letters received from the notified body and submit them together with the certificate.

In order to assist manufacturers and notified bodies in deciding whether a change in design or intended purpose should be considered significant, an interpretative document MDCG 2020-3 Rev.1 has been issued[15]. It describes possible significant and non-significant changes in the design or intended purpose of a device using specific examples and includes several illustrative diagrams in an annex.

Significant changes are considered to be, for example:

- extension of the intended purpose to other indications,
- a new target group of patients or users,
- new route of administration (new disease stage, new site of application, new route of administration, etc.),
- switching from analogue to digital control,
- switching from manual to software-controlled equipment,
- new stent pieces outside the previously certified lengths,
- significant changes to the operating system software,
- a change in implant material that is intended to come into direct contact with the patient's tissue,
- alteration of material of human or animal origin,
- change in the method of final sterilisation,
- change from non-sterile to sterile.

On the contrary, the following changes are considered insignificant:

- narrowing or removing certain indications,
- limiting the target group of patients or users,
- limitations on a particular method of application of the product,
- change of colour,
- design change for easier operation,
- changing the label or packaging material of a non-sterile device,
- change of primary packaging within the previously validated range,
- Software changes that introduce only non-therapeutic or non-diagnostic functions,
- new user interface of the software,
- change of material supplier within the defined specifications,
- changing the parameters of the sterilization cycle,
- change from single sterile packaging to double sterile packaging.

The document also describes changes that do not affect the design or intended purpose of the device. These are mainly administrative or organisational changes of the type:

- change of name, address or legal form of the manufacturer,
- changes in relation to the authorised representative,
- a new material supplier, provided the specifications are not changed.

15 MDCG 2020-3 Rev.1 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.

On the condition of no unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of public health protection

Regarding the compliance with this condition, although it is not expressly provided for in the transitional provision in question, it is clear that reference is made to the supervisory measures contained in Articles 95 and 98 MDR. That is to say, in the event that the competent supervisory authority concludes that the device presents an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of public health protection.

The question remains whether the finding of the competent authority and the related request for redress is sufficient for the non-fulfilment of this condition, or whether the restriction applies only in the event of failure to redress within a reasonable period of time, i.e. at the stage when the competent authority has already adopted the relevant prohibitive or restrictive measures. Only practice will tell the answer to this question, but it is likely to depend on the individual circumstances of each case.

On the condition to implement the QMS by 26 May 2024

Another condition is the obligation for the manufacturer to have a QMS in place in accordance with Article 10(9) MDR by 26 May 2024 at the latest. Manufacturers must subsequently draft documentation on their QMS as part of the application for conformity assessment. Compliance with the requirements related to the QMS, which cover post-market surveillance, market surveillance, vigilance and registration, is part of the relevant surveillance according to Article 120(3e) MDR, while the assessment of the compliance of the whole QMS with the MDR is carried out by the notified body as part of its conformity assessment activities[16].

Although the complete system documentation is to be submitted to the notified body designated under the MDR before the contract with the notified body is signed, the deadline for the contract is 26 September 2024. The fact that the manufacturer has prepared the system documentation does not mean that the QMS has actually been implemented. Solutions include requiring an internal audit of the QMS (including an internal audit by a third party), an assessment of the implementation of the system by a new notified body appointed under the MDR, or a combination of having a certification body certificate for compliance with the EN ISO 13485:2016 standard and conducting a gap analysis to assess how the MDR requirements are addressed beyond the scope of the standard, including correction of identified deficiencies. From the point of view of manufacturers, the reference to Article 10(9) MDR

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may be fatal, as the requirements of this provision are quite broad and the QMS must take into account a number of aspects such as risk management or clinical assessment according to the MDR (and it is therefore not a mere implementation of the requirements of EN ISO 13485:2016 or the introduction of a similar system). It is clear from this condition that the manufacturer must be 100% ready for the MDR as early as 26 May 2024.

On the condition of submitting a formal recertification application by 26 May 2024 and signing a contract with the notified body by 26 September 2024

In order to benefit from the extended transition period, the manufacturer must apply to the notified body for a conformity assessment under the MDR by 26 May 2024 at the latest. A full review of the application by the notified body is not required before a written agreement is signed and the application does not need to include technical documentation for each individual device. However, the application must clearly identify the manufacturer and the devices covered by the application, for example by listing the devices to be migrated to the MDR regime and, where applicable, the devices intended to substitute legacy devices. The information submitted with the application must enable the notified body to verify the qualification of the products as medical devices, their appropriate classification and the conformity assessment procedure chosen. When submitting the application, the manufacturer should indicate the timeline for the possible submission of the individual technical documentation and other relevant information.

As the manufacturer must comply with the QMS requirements of the MDR by 26 May 2024 at the latest, the application for a conformity assessment should include documentation of the manufacturer's QMS.

The notified body shall require a formal application signed by the manufacturer or the authorised representative and containing all the information and declarations of the manufacturer required by the relevant conformity assessment according to Annexes IX to XI MDR.

The subsequent contract between the notified body and the manufacturer shall take the form of a written agreement signed by both parties. The contract shall be kept by the notified body. The contract shall contain clear conditions and obligations enabling the notified body to act in the manner required under this Regulation, including the obligation of the manufacturer to inform the notified body of vigilance reports, the obligation of the notified body to suspend, limit or withdraw certificates issued and its information obligations.[17]

The chosen method of progressive submission of documentation can help to avoid undesirable situations where a manufacturer attaches a complete technical file to a recertification application, which the notified body will not get to review until, for example, two years later. The notified body may find a number of discrepancies arising from developments in the interim, both regulatory (e.g. change in MDCG documents) and technological (change in state of the art – **SOTA**). By agreeing on a timetable between the manufacturer and the notified body, an even distribution of work over time and an appropriate allocation of resources can also be achieved.

However, this model may also lead to a tendency for many manufacturers to postpone the preparation of individual technical documentation and leave their submission to the last minute. There is a risk that this will only delay the problem of insufficient capacity of notified bodies and, at the end of the extended transitional period, pressure

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will again be put on notified bodies in the form of newly submitted documentation that notified bodies will not be able to assess in time.

There is also a partial negation of the principle on which Regulation 2023/607 was based, namely that only prepared manufacturers can benefit from the extended transitional period. If the interpretation that the application for re-certification does not have to include a complete technical file is widely accepted, this will lead to another undesirable side effect. In fact, manufacturers who do not intend to transfer (some of) their legacy devices to the MDR regime at all, but only want to extend the period of time during which the legacy devices concerned can be legally traded, could ride this wave. The practice of the last months suggests that notified bodies are aware of and accept this reality.

The risk of creating pressure on notified bodies outlined above can only be avoided by a responsible approach by manufacturers and notified bodies. In the first place, it is important to avoid the wrong assumption that a manufacturer can completely avoid the preparation of a technical file before submitting a recertification application. In fact, the technical documentation must be linked to the QMS documentation, which is a mandatory annex to the recertification application. It should also be noted that careful and business-oriented notified bodies will certainly pressure manufacturers to submit the documentation as soon as possible. If manufacturers are not sufficiently prepared at the time of the recertification application and agree on a timetable with the notified body which they are subsequently unable to meet, cooperation with the notified body will not lead to the issue of the desired certificate. Furthermore, it should be noted that according to point 4.3(a) of Annex VII MDR, notified bodies are obliged to check the completeness of the application. According to

the MDR, the application must be accompanied by technical documentation. A non-legally binding opinion of the Commission can hardly 'trump' legally binding provisions that have gone through the proper legislative process. The interpretation of the European Commission may also be subsequently corrected and it may be too late to prepare the complete documentation at that point.

In view of the above, it is therefore clearly recommended to manufacturers not to delay the preparation of the technical documentation and ideally to submit it together with the application for re-certification, as required by the MDR. This is doubly true in the case of medical devices of higher risk classes, as the conformity assessment requires more time.[18]

Cancellation of the deadlines for "sell-offs"

In addition to addressing the dates and conditions for the placing legacy devices on the market, the MDR also needed to address the issue of the sell-off of old devices and legacy devices, i.e. the situation where a legacy device

18 See: MORAVOVÁ, Veronika. European Commission document on the new MDR transition periods addresses some contentious issues [online]. Porta Medica, 31 March 2023 [cited 2024-08-20]. Available from: https://www.portamedica.eu/post/the-european-commission-s-document-on-the-new-mdr-transition-periods-addresses-some-contentious-issu.

is placed on the market at a time when the end of the transition period is approaching. It was for these cases that an additional one-year period was initially set for the "sell-off" of all stocks in the distribution channel. Thus, it was not the case that all devices placed on the market legally could be delivered to end users without time limitation or only with an expiry date limitation. However, Regulation 2023/607 abolished this one-year period for "sell-offs" and introduced the possibility of making available on the market of legacy devices and old devices without limitation or until their expiry date.

MDR provisions applicable to legacy devices

The interpretation and application of the transitional provision, which sets out which MDR rules will also apply to legacy devices, is absolutely crucial for the operators concerned.

The transitional provision in question states that Chapter VII MDR, i.e. the rules on post-market monitoring, vigilance and market surveillance, apply to legacy devices. In addition, however, the obligation to register operators and devices under the MDR will also apply to legacy devices.

The MDCG has issued an interpretative document on this transitional provision[19] providing the following interpretation and recommendations:

- legacy devices are subject to all relevant requirements set out in Chapter VII MDR on post-market surveillance, market surveillance and vigilance,
- the relevant surveillance of legacy devices by notified bodies essentially is a continuation of the previous surveillance activities under previous directives, as notified bodies designed under previous directives are not designated to conduct MDR assessments,
- in their surveillance activities, notified bodies must take into account that manufacturers are subject to new requirements resulting from the transitional provisions of the MDR,
- there needs to be flexibility as regards notified bodies' involvement when reviewing applicable requirements as part of their 'appropriate surveillance', as the notified bodies responsible for the appropriate surveillance are not notified bodies involved in the conformity assessment procedure in accordance with Art. 52 MDR,
- legacy devices are subject to the requirements set out in Article 85 or Article 86 MDR based on their classification in accordance with the MDD,
- any change in the risk class of legacy devices under the MDR should not be taken into account during the transition period,
- active implantable devices subject to AIMDD should be considered as Class III devices for the purpose of applying the relevant MDR requirements during the transitional period.

With regard to the application of Article 86 MDR concerning a periodic safety update report (**PSUR**), the MDCG Ad Hoc Working Group on Transitional Provisions recommends the following procedure:

- legacy device manufacturers are subject to the requirement to develop and update a PSUR in accordance with Article 86 MDR,
- upon request, the manufacturer must make the PSUR available to the competent authorities (outside the Eudamed database),
- as part of the audit of the manufacturer's approved QMS, notified bodies must check that the manufacturer has made the necessary adjustments to comply

19 MDCG 2021-25 Regulation (EU) 2017/745 – application of MDR requirements to 'legacy devices' and to devices made available on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC.

with the new MDR requirements for post-market surveillance (**PMS**) and vigilance,

- manufacturers shall make PSURs available to their notified bodies as part of surveillance audits (outside the Eudamed database) so that the notified body can verify that the approved QMS and design remain in compliance with the certificate issued under MDD or AIMDD,
- existing contracts between the notified body and the manufacturer should cover the surveillance activities to be carried out by the notified body during the transitional period,
- therefore, the addition of the PSUR to the documentation to be provided to notified bodies in the framework of surveillance audits should not be a reason to amend these existing contracts or to charge additional fees,
- once legacy devices are certified in accordance with the MDR, the PSURs developed during the transition period should continue to be updated,
- the PSUR will then have to be communicated to and, where appropriate, reviewed by the new notified body involved in the conformity assessment procedure set out in Article 52 MDR in accordance with Article 86 MDR.

In addition to the requirements set out in Chapter VII MDR, other requirements of the MDR should apply to legacy devices, insofar as these requirements relate in any way to post-market surveillance, market surveillance or vigilance, as well as those addressing the registration of operators and devices.

Manufacturers and importers are subject to the general obligations to place on the market only devices that comply with the MDR (Articles 10(1) and 13(1) MDR). In the case of legacy devices, compliance with the MDR means compliance with the MDD or AIMDD and the additional requirements under Article 120 MDR. In addition, Article 10(10), (12) to (15) MDR apply to manufacturers, Article 11(3)(c) to (g) MDR apply to authorised representatives and Article 14(2) last subparagraph and (4) to (6) MDR apply to importers.

MDR requirements that do not concern post-market surveillance, market surveillance, vigilance, registration of operators and devices should in principle not apply to legacy devices and relevant operators. These are e.g. Article 15 (person responsible for regulatory compliance), Article 16(3) and (4) (provisions for cases where the importer, distributor or other entity takes over the obligations of manufacturers), Article 18 (implant card), Article 25 (identification and traceability of devices in the supply chain), Article 27 (UDI system) and Article 32 MDR (obligations relating to the summary of safety and clinical performance). However, economic operators can opt to fully comply with the MDR on a voluntary basis and follow all its provisions; this makes particular sense in a situation where an economic operator trades both legacy devices and devices under the MDR regime and wishes to apply uniform practices across its portfolio.

In the context of the application of some MDR provisions to legacy devices, it is necessary to mention and interpret the situation of systems and procedure packs. For those consisting only of legacy devices and for which a declaration has been made before 26 May 2021 in accordance with Article 12 MDD, the MDR provisions regulating systems and procedure packs (Article 22) do not apply. In contrast, systems and procedure packs that combine legacy devices and MDR devices (e.g. Class I devices not covered by Article 120 MDR) are covered by Article 22 MDR, while legacy devices as such included in a system or procedure pack are covered by the transitional provisions of Article 120 MDR.

Table showing MDR requirements that do or do not apply to legacy devices[20].

20 MDCG 2021-25 Regulation (EU) 2017/745 – application of MDR requirements to 'legacy devices' and to devices made available on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC.

MDR requirement	Application in the case of legacy devices
Article 10(10), (12) to (15) – manufacturer's obligations: PMS, compliance with MDR, vigilance, demonstration of conformity, cooperation, subcontractors	**YES** (*'compliance with the requirements of this Regulation'* means, for legacy devices, compliance with MDD or AIMDD and the additional requirements under Article 120(3) to (3e) MDR)
Article 11(3)(c) to (g) – duties of the authorised representative: registration in Eudamed, PMS, cooperation, vigilance	**YES** (*'compliance with the requirements of this Regulation'* means, for legacy devices, compliance with MDD or AIMDD and the additional requirements under Article 120(3) to (3e) MDR)
Article 11(7) – Competence of the competent authority for the authorised representative	**YES**
Article 13(2), second subparagraph, paragraphs 4, 6 to 8, 10 – importer's obligations: identification of the manufacturer and the authorised representative, registration in the Eudamed database, PMS, cooperation, vigilance	**YES** (*'compliance with the requirements of this Regulation'* means, for legacy devices, compliance with MDD or AIMDD and the additional requirements under Article 120(3) to (3e) MDR)
Article 14(2), last sub-paragraph, paragraphs 4 to 6 – distributor's obligations: compliance with MDR, PMS, cooperation, vigilance, demonstration of compliance	**YES** (*'compliance with the requirements of this Regulation'* means, for legacy devices, compliance with MDD or AIMDD and the additional requirements under Article 120(3) to (3e) MDR)
Article 15 – person responsible for regulatory compliance	**NO**
Article 16(3) and (4) – translation and repackaging by the importer or distributor	**NO**
Article 18 – Implant card and information to be supplied to the patient with an implanted device	**NO** (without prejudice to national regulations on implant cards and information to be supplied applicable to legacy devices)
Article 22 – systems and procedure packs	**YES** for systems and procedure packs combining legacy devices and MDR devices
Article 25 – Identification within the supply chain	**NO** (without prejudice to supply chain traceability requirements that apply to legacy devices under other rules, such as the market surveillance of goods regulations or the General Product Safety Directive)
Article 27 – UDI	**NO** (in this respect, see also MDCG 2019-5 on the registration of legacy devices in the Eudamed database)

MDR requirement	Application in the case of legacy devices
Article 29 – registration of devices	**In principle YES**, but as the Eudamed database is not fully functional, special transitional provisions apply in accordance with Articles 122 and 123(3)(d) and (e) MDR.
Article 31 – Registration of economic operators	**In principle YES**, but as the Eudamed database is not fully operational, specific transitional provisions apply in accordance with Articles 122 and 123(3)(d) and (e) MDR.
Article 32 – Summary of safety and clinical performance	**NO**
Articles 83 and 84 – PMS system and PMS plan	**YES** (except for requirements relating to obligations that cannot be applied, e.g. Article 83(3)(d) – summary of safety and clinical performance (**SSCP**); no requirement for full revision of technical documentation in accordance with Annexes II and III)
Article 85 – PMS report (Class I devices)	**YES** (the classification of Class I devices is governed by the MDD classification rules, i.e. Article 85 applies to Class I legacy devices, although these devices may be classified in a higher class under the MDR)
Article 86 – PSUR (Class IIa, IIb and III devices)	**YES** (manufacturers prepare and update PSURs; they must be taken into account by the notified body designated under the MDD or AIMDD in surveillance audits, see further explanation above)
Article 87 – Serious incidents reporting	**YES**
Article 88 – trend reporting	**YES** (trend reporting was already part of the vigilance system established under MDD or AIMDD)
Article 89 – Serious Adverse Event Analysis and field safety corrective action (**FSCA**)	**YES**
Article 90 – analysis of vigilance data	**YES**
Article 91 – Implementing acts	**YES**
Article 92 – Eudamed vigilance module	**In principle YES**, but as the Eudamed database is not fully functional, special transitional provisions apply in the area in accordance with Articles 122, 123(3)(d) and (e) MDR
Article 93 – market surveillance activities	**YES**

MDR requirement	Application in the case of legacy devices
Article 94 – evaluation of non-conformities	**YES** (*'compliance with the requirements of this Regulation'* means, for legacy devices, compliance with MDD or AIMDD and the additional requirements under Article 120(3) to (3e) MDR)
Articles 95, 96 and 97 – devices presenting an unacceptable risk; evaluation of national measures; other non-compliance	**YES** (*'compliance with the requirements of this Regulation'* means, for legacy devices, compliance with MDD or AIMDD and the additional requirements under Article 120(3) to (3e) MDR)
Article 98 – Preventive health protection measures	**YES**
Article 99 – Good administrative practice	**YES**
Article 100 – electronic system on market surveillance	**YES**

In this context, we also consider it important to mention which provisions of the MDR apply to old devices. Opinion of MDCG Transitional Provisions working group suggests that Articles 93 to 100 MDR, which set out the rights and obligations of competent authorities with regard to market surveillance activities, also apply to old devices. This allows competent authorities to check that devices comply with the rules in force at the time they were placed on the market and to take appropriate action against non-compliant or unsafe devices. Practical aspects regarding market surveillance activities in relation to "old" devices should be clarified in the MDCG Market Surveillance Working Group[21].

Surveillance of legacy devices and its transition to a new notified body

The transitional provision states that the notified body that issued the certificate[22] remains responsible for the relevant market surveillance activities with regard to all applicable requirements relating to the devices it has certified and must be able to take all necessary measures in relation to those requirements. It is now possible that these responsibilities may be taken over by a new notified body in agreement with the manufacturer, at the earliest from 26 May 2024, subject to an agreement between the manufacturer and the new notified body and, if feasible (which will not be the case, for example, if it has already ceased its activities[23]), the notified body that issued the relevant certificate. It is made clear that the new notified body does not assume responsibility for the conformity

21 MDCG 2021-25 Regulation (EU) 2017/745 – application of MDR requirements to 'legacy devices' and to devices made available on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC.

22 On the basis of a valid design, i.e. national authorisation in conjunction with notification/notification at EU level.

23 Extension of the MDR transitional period and removal of the "sell-off" periods: Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, REV. 1.

assessment carried out by the original notified body issuing the certificate. In the absence of such an agreement, the new notified body assumes these responsibilities from 26 September 2024 at the latest, and in the case of the device intended to substitute the legacy device, this is the supervision of the device being replaced.

The arrangement for the transfer of supervision should follow the same principles set out in Article 58(1) MDR and should include the transfer of the relevant documentation from the withdrawing notified body to the incoming notified body. The agreement between the manufacturer, the withdrawing notified body and the incoming notified body (the 'tripartite agreement') should also address the possibility for the MDR notified body to suspend or withdraw the certificate issued by the MDD/AIMDD notified body if duly justified.[24]

An issue that relates to the transfer of the surveillance obligation between the original and the new notified body is the obligation to modify the labelling of the device, specifically the placement of the notified body identification number. The Commission has taken the view[25] that it is not necessary to modify the labelling, but where feasible and taking into account the details of the surveillance transfer agreement, the number of the new notified body may be provided for the marking of the legacy device.

Up-classified devices

Both under the second corrigendum of the MDR[26], and after the entry into force of Regulation 2023/607, certain devices falling within risk class I of the MDD for which a declaration of conformity was drawn up before 26 May 2021 and for which the conformity assessment procedure under the MDD did not require the involvement of a notified body, but which the MDR already requires, may be placed on the market in the legacy devices' regime under certain conditions. These are reusable surgical instruments (risk class Ir) or devices that were previously classified as risk class I under the MDD and now belong to higher risk classes. The term "up-classified devices" has been established for these devices and they can be placed on the market or put into service until **31 December 2028**.

The category of up-classified devices may also include Class III custom-made implantable devices for which the MDD did not require the involvement of a notified body in the conformity assessment process, whereas the MDR does. Under the new transitional provision, custom-made Class III implantable devices may be placed on the market or put into service without the relevant certificate until **26 May 2026**, provided that the manufacturer has submitted an application for conformity assessment to a notified body by 26 May 2024 at the latest and has signed a written agreement with that notified body by 26 September 2024 at the latest. Interestingly, the MDR does not mention that custom-made Class III implantable devices must also comply with the conditions set out in Article 120(3c)(a) to (d).

For up-classified devices, the question has arisen in practice whether and to what extent the obligation to supervise these devices placed on the market under the legacy device regime by notified bodies applies to these devices, since they have not been certified under the original

24 Extension of the MDR transitional period and removal of the "sell-off" periods: Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, REV. 1.

25 Extension of the MDR transitional period and removal of the "sell-off" periods: Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, REV. 1.

26 Corrigendum to 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.

legislation in force and thus there is seemingly nothing to supervise. A recent MDCG opinion made it clear that these devices are not subject to surveillance[27].

Parallel placing on the market of legacy devices and the devices that replace them

Following the amendment of the transitional provision, the MDR explicitly provides for the possibility of parallel placing on the market of legacy devices and MDR compliance-assessed devices that replace them. The Commission allows a manufacturer that successfully completes the recertification of a device under the MDR to market its legacy devices (the devices being replaced) in parallel until the end of the extended transition period. Such an interpretation seems to contradict the terminology used in the MDR, which refers to a device that "replaces" a legacy device. However, the new approach to allow such overlapping will probably solve the potential problem of manufacturers with stock of legacy devices after re-certification and avoid their unnecessary disposal. At the same time, however, it may lead to traceability problems for specific devices and cause some lack of clarity in the market.

27 MDCG 2022-4 Rev. 2. 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.

Products without an intended medical purpose

In the context of the extension of the transitional provisions for legacy devices, we consider it important to point out that the transitional provisions for products without an intended medical purpose have also been extended (see Annex XVI MDR).

The MDR requires the Commission to adopt common specifications for groups of products without an intended medical purpose, which cover at least the application of risk management as defined in the general safety and efficacy requirements and, where necessary, clinical safety evaluation. As from the date of applicability of the common specifications, the MDR will also apply to this type of products.

Common specifications for products without an intended medical purpose were issued later than the MDR, in December 2022 in the form of the Commission Implementing Regulation (EU) 2022/2346 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices. The applicability of this Regulation, and therefore the applicability of the MDR to this type of products, was specified in the transitional provisions of Regulation 2022/2346. However, in view of the extension of the MDR transition periods, the Commission concluded that the transitional provisions for products without an intended medical purpose should reflect this fact and their transition periods should be aligned with the new MDR transition periods applicable after the adoption of the amending Regulation 2023/607.

Therefore, in June 2023, Commission Implementing Regulation (EU) 2023/1194 amending Implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council was adopted.

Products without an intended medical purpose for which the manufacturer intends to perform a clinical investigation

Products without an intended medical purpose that undergo a clinical investigation to confirm compliance with the MDR, which must involve a notified body, will continue to be placed on the market or put into service until 31 December 2029 (instead of the original date of 22 June 2028). However, the conditions must be met that the product has already been marketed on the EU market before 22 June 2023, continues to comply with the requirements of European and national law that applied to it before that date, and there have been no significant changes to the design and intended purpose.

However, the possibility to place the product on the market until 31 December 2029 will only apply to those products that will progressively fulfil the sub-conditions set out in the Regulation for each specific part of this period:

- The product will not be allowed to be placed on the market between 22 June 2024 and 22 December 2024 unless the sponsor has received a notification from the Member State pursuant to Art. 70(1) or (3) MDR confirming that the application for a clinical investigation of the product is complete and that the clinical investigation falls within the scope of the MDR. If he has not received this confirmation by 21 June 2024, he will not be allowed to place the product on the market.
- In addition, the product will not be allowed to be placed on the market between 23 December 2024 and 31 December 2027 (instead of the original 22 June 2026) unless the sponsor has started a clinical

investigation. If he does not do so, he can no longer place the product on the market.

- The product will not be allowed to be placed on the market between 1 January 2028 (instead of the original 23 June 2026) and 31 December 2029 (instead of the original 22 June 2028) unless the manufacturer has signed a written agreement with the notified body to carry out a conformity assessment in accordance with Annex VII, Section 4.3, second paragraph MDR. Therefore, signing a certification agreement with a notified body according to the MDR is a necessary condition for the product to be placed on the market or put into service from 1 January 2028 to 31 December 2029.

Products without an intended medical purpose for which the manufacturer does not intend to perform a clinical trial

Products without an intended medical purpose, which will not be subject to a clinical investigation, but for which a notified body must be involved in the conformity assessment, may be placed on the market or put into service until 31 December 2028 (instead of the original date of 22 June 2025). Again, the product must have been placed on the EU market before 22 June 2023, it continues to comply with the requirements of European and national law that applied to it before that date, and there have been no significant changes to the design and intended purpose. However, a further restrictive condition in relation to the sub-period also applies here: the manufacturer will only be allowed to place the product on the market or put it into service between 1 January 2027 (instead of the original 22 September 2023) and 31 December 2028 (instead of the original 22 June 2025) if he has already signed a written agreement with a notified body to carry out a conformity assessment in accordance with Annex VII, Section 4.3, second paragraph MDR. In other words, he may place the product on the market without further restrictions until 31 December 2026, subject to the substantive conditions set out above, but if he wishes to place it on the market or put it into service after that date until 31 December 2028, he must have already signed a certification agreement with a notified body under the MDR.

Products without an intended medical purpose with a certificate issued under the MDD

A product without an intended medical purpose that has previously been certified by a notified body in accordance with the MDD, where such a certificate has expired between the entry into force of the MDR (26 May 2021) and the entry into force of the amending Regulation 2023/607 (20 March 2023), and where none of the conditions for renewal of the certificate under Art. 120(2) (a) and (b) of the second subparagraph MDR has occurred (i.e. a recertification contract has not been signed with a notified body or the product has not received one of the specified exemptions under Art. 59(1) or 97(1) MDR), it may continue to be placed on the market until 31 December 2027 or 31 December 2028 (depending on the risk class), provided that the conditions of Art. 120(3c), (3d) and (3e) MDR are met:

- the product continues to comply with the MDD;
- there have been no significant changes in the design and intended purpose;
- the product does 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 manufacturer has established a QMS in accordance with Art. 10(9) MDR no later than 26 May 2024;
- the manufacturer has submitted a formal application for conformity assessment in accordance with Annex VII, Section 4.3, first subparagraph MDR to

the notified body no later than 26 May 2024, 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, second subparagraph MDR;
- the MDR will apply to post-market monitoring, market surveillance, vigilance, registration of economic operators and devices and
- the notified body that issued the product certificate will remain responsible for the corresponding surveillance unless a new notified body is agreed.

With regard to this category of products without an intended medical purpose, it is not clear from the text of the Regulation which cases it is intended to cover in practice. It appears that in the past the product in question was classified as a higher risk class or class Is medical device, for which it received a certificate from a notified body, but after the MDR came into force it clearly falls into the category of products without an intended medical purpose. Theoretically, this could include products that have received a certificate from a notified body when they should not have; a product that previously had both a medical and a non-medical intended purpose and was therefore qualified as a medical device under the MDD but the manufacturer changes the newly designated intended purpose to a non-medical purpose only; a product that has both a medical and a non-medical intended purpose (see Art. 1(3) MDR, which presupposes the existence of such products); or products that were medical devices when the MDD was in force, even though they did not have an equal or greater clinical benefit compared to SOTA, but under the optics of the MDR, they would no longer be able to demonstrate a clinical benefit and thus a clinical investigation of the product would not be allowed.

Eudamed database

Since the MDR applicability, the new system of medical device regulation has faced two challenges, both of which eventually led to the amendment of the regulation.

In addition to the lack of preparedness of manufacturers and notified bodies to recertify medical devices within the originally intended timeframes, which we have outlined in the previous chapter, another problem of the MDR has been the timely launch of the Eudamed database.

The Eudamed database is designed as a hub for all medical device market data in the EU, with the aim of improving, unifying and streamlining the exchange of device information across operators, regulators and EU Member States.

The Eudamed database existed in some form before the MDR came into force, but was only accessible to the competent authorities of the Member States and the Commission. In contrast, the main idea behind the new Eudamed database was to expand the volume of information and make it also available to economic operators, healthcare professionals and the general public.

It is precisely the expansion of the range of information to be collected and provided by the Eudamed database, together with the condition that the use of the database will be mandatory only when it is fully functional, i.e. when all six modules are ready, and even after a certain transitional period, that has led to the fact that even seven years after the adoption of the MDR and three years after its applicability, the Eudamed database has not been launched and its use as intended by the original MDR has been realistically postponed until 2029. It should be noted that the timetable for the launch of the Eudamed database has been communicated and updated by the EU several times over the years, only to be changed again after some time. This never-ending story and constant change of date has led to long-lasting frustration for all stakeholders.

That is why the European Commission has come up with another piece of legislation to address the unfortunate situation with the European medical device database. This is Regulation (EU) 2024/1860, published in the Official Journal of the EU on 9 July 2024.

In addition to the Eudamed database, the Regulation addresses two other topics, namely the introduction of an information obligation in the event of interruptions in the supply of medical devices and the extension of the transitional provisions for legacy IVDs in a similar form to that brought by Regulation 2023/607 for general medical devices. However, in the context of this publication, we will only address in detail the issue of the Eudamed database.

Existing rules for mandatory use of the Eudamed database

According to the current MDR rules, the Eudamed database can only be used on a mandatory basis once the database is fully operational, i.e. once all six modules are completed and operational. These modules are:

- economic operators,
- UDI and device registration,

- notified bodies and certificates,
- market surveillance,
- vigilance and post-market surveillance,
- clinical trials.

Three modules of the Eudamed database are now ready and running for voluntary use (operators, UDI and device registration, notified bodies and certificates). The market surveillance and vigilance and post-market surveillance modules should be completed during 2024. However, the last module – clinical trials – will not be completed until Q3 2026 at the earliest. Applying the current MDR provisions, the Eudamed database would therefore not be mandatory for use until Q2 2029 at the earliest.

Eudamed database after the adoption of the amending regulation

The amending regulation foresees the gradual introduction of the individual modules of the database after they have been checked and declared functional (independently of the other modules). Finished modules could be in use as early as Q4 2025.

This removes the concept that the use of the Eudamed database can only become mandatory once all its modules have been declared fully functional. Instead, it allows for the gradual introduction of individual modules once they have been checked and found to be functional. The Commission will continue to publish this notification in the Official Journal of the European Union.

Changes to a coordinated assessment procedure for clinical investigations

In the context of the gradual roll-out of the Eudamed database, it was necessary to modify the provision concerning clinical trials conducted in several EU Member States. The procedure under Article 78 MDR, which deals with this issue, could be used on a voluntary basis until 25 May 2027, after which it was made mandatory. The amending Regulation changes this and provides that the Article 78 MDR procedure must be followed after five years from the date on which the Commission declares the clinical trials module operational in the Official Journal of the EU. States in which a clinical trial is to be conducted may also apply the Article 78 MDR procedure earlier on a voluntary basis, but not earlier than 6 months after the Commission notification.

Changes to transitional provisions

In view of this conceptual change, it was also necessary to amend the transitional provisions (Articles 120(8), 122 and 123(3) MDR), which in some way relate to the Eudamed database. The new transitional provisions also address which devices and which certificates have to be registered in Eudamed and the timeframe applicable to them.

Amendments to Article 120(8) MDR

The transitional provision that dealt with the registration and record-keeping obligations of manufacturers, authorised representatives, importers and notified bodies in relation to the launch of the Eudamed database is removed. This transitional provision implied that if a manufacturer, authorised representative or importer complies with its device and economic operator registration obligations in the Eudamed database in the interim period from its official launch to 18 months from that date, then it is

deemed to have complied with the related requirements of the national legislation transposing the MDD or AIMDD. The same has been provided for notified bodies in relation to the entry of all information concerning certificates issued, including amendments and additions thereto, and certificates suspended, renewed, refused, withdrawn or otherwise restricted into Eudamed. However, this transitional provision becomes irrelevant in the context of the change in the gradual roll-out of the different modules of the Eudamed database and the modification of the transitional provision of Article 123 MDR, and is therefore removed from the MDR.

Amendments to Article 122 MDR

As the MDR replaced the previous directives, i.e. the MDD and AIMDD, the mandatory applicability date of the MDR resulted in the repeal of these directives, but with a few partial exceptions.

One of the exceptions were the provisions on vigilance and clinical trials, which were initially repealed on the date of the official launch of the Eudamed database.

Another of the exceptions were the provisions concerning the registration of devices and operators and the notification of certificates of compliance, which were initially repealed 18 months after the official launch of the Eudamed database.

The two exemptions are now aligned and the provisions of the two Directives are repealed on the date of applicability of the relevant Eudamed module.

Amendments to Article 123 MDR

This transitional provision sets out an important point, namely how to determine the date from which each module will be applicable once it has been declared functional. The date of applicability of each module will be 6 months after the publication of the Commission's notice in the Official Journal of the EU.

No later than twelve months after the publication of the notification of the full functionality of the UDI and device registration module, data on devices placed on the market after that date shall be entered into it. This obligation applies to all MDR-assessed medical devices, except custom-made devices, and also to all legacy devices, except custom-made devices, unless the MDR-assessed device that replaces them is already registered in Eudamed.

No later than 18 months after the publication of the notification of the full functionality of the notified bodies and certificates module, notified bodies must enter into it all information concerning certificates issued, namely those related to medical devices with conformity assessed according to the MDR, except for custom-made devices (for these devices only the last relevant certificate and the notified body decision concerning it, if any, shall be indicated).

A summary of safety and clinical function data and related competent authority information shall be entered in the relevant module for all MDR-assessed devices, except

custom devices and legacy devices, except custom devices, unless the MDR-assessed device that replaces them is already registered in Eudamed and only if their certificate is entered in Eudamed.

Where the manufacturer is required to submit a vigilance report or a regularly updated device safety report to the vigilance and post-market surveillance module, he shall also register the device to which the report or report relates in the UDI and devices module. This provision shall not apply to legacy devices.

Assessment of the benefits of the amending regulation

Speeding up the launch of the database will be particularly beneficial for the regulatory authorities of the Member States, who will be relieved of the complex agenda of maintaining national databases. It will also bring considerable relief to healthcare providers, especially hospitals. For them, the situation created by Regulation 2023/607, and its imminent counterpart for IVDs, i.e. the overlap of legacy devices and devices with compliance assessed under the new regulations, was unbearable, as they were dependent on individual communication with their supplier and complex verification of the information submitted when purchasing medical devices and in the procurement process when checking regulatory documents and verifying

compliance with the conditions for placing the device on the market. The launch of modules with information on devices, certificates and unique identifiers will make their work much easier.

On the other hand, manufacturers who have not yet had to fulfil many of the obligations associated with the operation of the Eudamed database due to the dismal development of the full functionality of the database should take notice. They will therefore have to put in place internal processes and capacity for this agenda earlier than they had anticipated in autumn 2023 based on the Commission's published estimate[28]. Ultimately a functional Eudamed database, albeit not in its full form, will also benefit this segment; it will make it easier for all honest operators to comply with the requirements for transparency and traceability of medical device movements.

28 MDR/IVDR Eudamed Roadmap [online]. 2023 [cited 2024-06-05]. Available from: https://health.ec.europa.eu/document/download/04ce2012-97df-4dd0-8a39-d4f6993b9e16_en?filename=md_eudamed_roadmap_en.pdf.

Conclusion

The last seven years have witnessed significant turbulence in the medical devices sector, accompanied by numerous delays in certain processes and non-legislative and legislative solutions to the problems that have arisen. As a result of these changes, the medical device sector has become a completely unclear and unpredictable environment for many stakeholders. Moreover, the measures taken have brought question marks rather than clear answers to the whole process.

We hope that this publication has brought greater clarity to the MDR transition process for all readers, helped them to better understand both regulations and their specific implications for the supply and regulatory sectors, and provided a basis for effectively navigating the complex and dynamic changes that medical device regulation is undergoing.