

● Implementing the European Union Medical Devices Regulations

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By Royal Charter



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Introduction

The European Union (EU) Medical Devices Regulation¹ (EU 2017/745) (MDR) and the In Vitro Diagnostic Medical Devices Regulation² (EU 2017/746) (IVDR), now apply. Important terms used in the regulations are 'entry into force' and 'date of application'.

The publication of the text in the Official Journal of the European Union was on 5 April 2017. The 'entry into force' was the date when each regulation came into effect, twenty days after publication. The 'date of application' reflects the date from which the requirements apply and the Active Implantable Medical Devices Directive (AIMDD - 90/385/EEC), Medical Devices Directive (MDD - 93/42/EEC) and In Vitro Diagnostic Medical Devices Directive (IVDD - 98/79/EC) were repealed.

Since the publication of the legal texts, there have been corrigenda issued. These correct small errors and amendments that have been made to change the date of application and transitional arrangements. The changes in dates are in response to the challenges created or exacerbated by the COVID-19 pandemic impacting on manufacturers' ability to undergo conformity assessment of technical documentation. These challenges include limited notified body capacity, particularly for the IVDR, and limited availability of guidance documents.

The transitional arrangements for the regulations allow for medical devices and in vitro diagnostic medical devices (IVDs), with valid certificates or declarations of conformity to the Directives, to continue to be placed on the market for finite periods. These periods depend on the classification of the device or IVD. For all classes of devices and IVDs, there are three provisos to the extension of validity of certificates or declarations of conformity.

- Firstly, that some requirements of regulations will apply to devices with valid certificates and declarations of conformity under the Directives. These requirements include those for post-market surveillance (PMS), vigilance reporting, market surveillance by national authorities and registration.
- Secondly, that no significant changes are made to the device or intended use.
- Thirdly, that the notified body that issued the certificate continues to be responsible for surveillance of devices it has certified.

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.

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.





For the MDR, the approved text of an amending regulation³ was published on 24 April 2020. As well as postponing the date of application of the MDR to 26 May 2021, the amending regulation also delayed or extended, as applicable, dates or deadlines for:

- repeal of the AIMD and MDD;
- drawing up a declaration of conformity under the MDD for a class I device requiring notified body involvement;
- availability of the common specification of products without an intended medical purpose;
- availability of the common specification for reprocessing of single use devices;
- publication of the notice on the functionality of the EUDAMED database;
- Member States publishing their rules on penalties for infringements of the MDR;
- permission to designate notified bodies to the MDR whilst the AIMD and MDD remain in force;
- ongoing clinical investigations under the AIMD or MDD to continue;
- publication of guidance on the operation of expert panels established under the MDR.

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.

An amendment to the IVDR⁴ changed the date of application for certain classes of IVDs. The amending Regulation did not change any requirements contained in the original IVDR, only the dates from which some of those requirements apply. There is no change for CE-marked devices that do not require notified body involvement under the IVDR, or for new devices that do not have either a notified body certificate or a declaration of conformity under the IVD Directive. For these types of devices, the IVDR applied from 26 May 2022 as planned. For other IVDs, there are staggered arrangements quite similar to that introduced for legacy devices under the MDR. IVDs that were lawfully placed on the market under the IVD Directive before 26 May 2022 can continue to be made available or put into service until 26 May 2025. IVDs that were self-certified or self-test under the IVD Directives but require certificates from a notified body under the IVDR had the date of application changed to later years. The additional time increases as the risk associated with the devices decreases, as follows:

- 26 May 2025 for Class D;
- 26 May 2026 for Class C; and
- 26 May 2027 for Class B and Class A, sterile.

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.

The European Commission's Medical Device Coordination Group (MDCG) undertook a survey on notified body certification and application activities under the Medical Devices Regulation (EU 2017/745) (MDR) and In Vitro Medical Devices Regulation (EU 2017/746) (IVDR). Its findings revealed the following problems in the transition to the MDR⁵.

- A significant number of certificates for legacy devices expire in 2024 for medical devices. At the current rate of certification, all existing products cannot be transitioned by the current deadline.
- The overall capacity of notified bodies remains insufficient to carry out the required conformity assessment tasks.
- Many manufacturers were not ready to meet the requirements of the MDR by the end of the transition period.

The European Commission presented a proposal to further extend the transition period for the MDR in order to maintain patients' access to a wide range of medical devices while ensuring the transition to the new regulations⁶. The extension will be staggered depending on the risk class of the devices. There are conditions associated with these extensions, including that the manufacturer has to have taken steps to transition to the MDR in order to benefit from the additional time. It also proposes to delete the deadline in both the MDR and IVDR for 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 proposal has been agreed by the European Council and the European Parliament and has been adopted as Regulation (EU) 2023/607.⁷ This Regulation entered into force on 20 March 2023, the day of its publication in the Official Journal of the European Union.

⁶ 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 2023/0005 (COD).

⁷ Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (Text with EFA relevance).

As a result, Article 120(2) of the MDR has been amended. This extends the validity of certificates issued under the Directives for active implantable medical devices and medical devices (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; notified bodies are not required to change the date on the individual certificates. For 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 under the MDR.



In addition, it is proposed that 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 since considered to be based on well-established technologies); and
- 31 December 2028 for medium and lower risk devices (other class IIb and class IIa devices, and class I devices with a measuring function, are sterile, are reusable surgical instruments or software as a medical device, provided that the declaration of conformity was signed before 26 May 2021).

The extended transition is subject to the following proposed conditions:

- the devices continue to comply with the applicable Directives;
- the devices do not undergo significant changes in the design and intended purpose;
- the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to public health;
- no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with the MDR; and

⁵ Notified Bodies Survey on certifications and applications (MDR/IVDR) https://health.ec.europa.eu/system/files/2022-10/md_nb_survey_certifications_applications_en.pdf

- no later than 26 May 2024, a formal application has been submitted under 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
- Notwithstanding the proposed extensions to the transitional periods, the requirements for PMS and vigilance apply to legacy devices placed on the market with certificates of conformity to the previous Directives.
- BSI has published several white papers describing the MDR, the IVDR and how to prepare for them.^{8 9 10 11 12 13 14 15}

The extent and implications of the changes introduced by the regulations are significant. Planning is necessary to complete the activities within prescribed times, particularly as there are a number of areas where the availability of external resources will be limited.

Planning for implementation of these regulations is a classic project management activity to identify what has to be done, in what order, by whom and by when, and how progress will be monitored. The detail of the project plan will vary from organization to organization depending upon their role(s) under the Regulation(s), their size, the way that they are organized and managed, the types of medical devices for which they have regulatory accountability, and their strategic business intentions. Therefore, it is not possible to create a single implementation plan that would be applicable to the wide range of organizations affected by the Medical Devices Regulation.

The initial version of this paper was prepared prior to the entry into force of the regulations and focused on the practical aspects of implementation and highlighted some of the major changes. It discussed decisions that need to be made by affected organizations and included questions to ask about your organization's preparedness to come into compliance with the new requirements. This was intended to assist in developing an implementation plan. While this paper was focused on the MDR, in many aspects, the requirements of the IVDR parallel the MDR and the material presented was intended to be as generic as possible and apply in large part to both regulations. With the date of application for the MDR having now passed, this updated paper is intended to assist manufacturers with legacy products on the market with certificates of conformity to the Directives to assess their plans to transition to the regulations. It is also intended to assist manufacturers entering the EU market with devices for the first time under the regulations.

This paper addresses considerations for implementation in a number of areas:

- **scope** – addressing the range of activities that are undertaken and requirements for economic operators (manufacturers, authorized representatives, importers and distributors);

- **product portfolio** – dealing with existing products and their technical documentation, including clinical evidence;
- **new product development** – considering products in the development pipeline;
- **design and development** changes to devices;
- **Quality management system (QMS)** – looking at responsibilities of the person responsible for regulatory compliance, ISO 13485:2016 certification and lifecycle management;
- **technical documentation** – understanding the content and maintenance;
- **labelling** – concerning unique device identification, implant cards and labelling changes;
- **Post-market surveillance (PMS)** – looking at PMS plans, periodic safety update reports (PSURs) or post-market surveillance reports, and post-market clinical follow-up (PMCF);
- **availability of EUDAMED**, the European database for medical devices;
- **external issues** – considering implementing and delegated acts and notified body interactions.

8 How to prepare for and implement the IVDR – Dos and don'ts

9 Planning for implementation of the European Union Medical Devices Regulations – Are You Prepared?

10 General Safety and Performance Requirements (Annex 1) in the New Medical Device Regulation: Comparison with the Essential Requirements of the Medical Device Directive and Active Implantable Device Directive

11 Technical Documentation and Medical Device Regulation: A Guide for Manufacturers to Ensure Technical Documentation Complies with EU Medical Device Regulation 2017/745

12 European Union Medical Device Regulation and In Vitro Device Regulation: unique device identification: What is required, and how to manage it

13 Guidance on MDCG 2019-9: Summary of Safety and Clinical Performance

14 Person responsible for regulatory compliance

15 Clinical evaluation under the EU MDR

Scope

The regulations extended the scope of the legislation beyond requirements of the manufacturer. The requirement remains for a manufacturer located outside the European Union to have an authorized representative within the European Union. Additional requirements have been added to cover the supply chain responsibilities of other economic operators, namely the distributor, in all cases, and the importer, where the manufacturer is located outside the European Union.

The key points in the definitions of these terms are:

- **manufacturer** – produces or fully refurbishes a device, or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;
- **authorized representative** – acts on the manufacturer's behalf in relation to specified elements of the manufacturer's obligations and is established within the EU with a written mandate from a manufacturer located outside the EU;
- **importer** – places a device from outside the EU on the EU market and is established within the EU; and,
- **distributor** – makes a device available on the market, up until the point of putting into service, but is not the manufacturer or the importer.

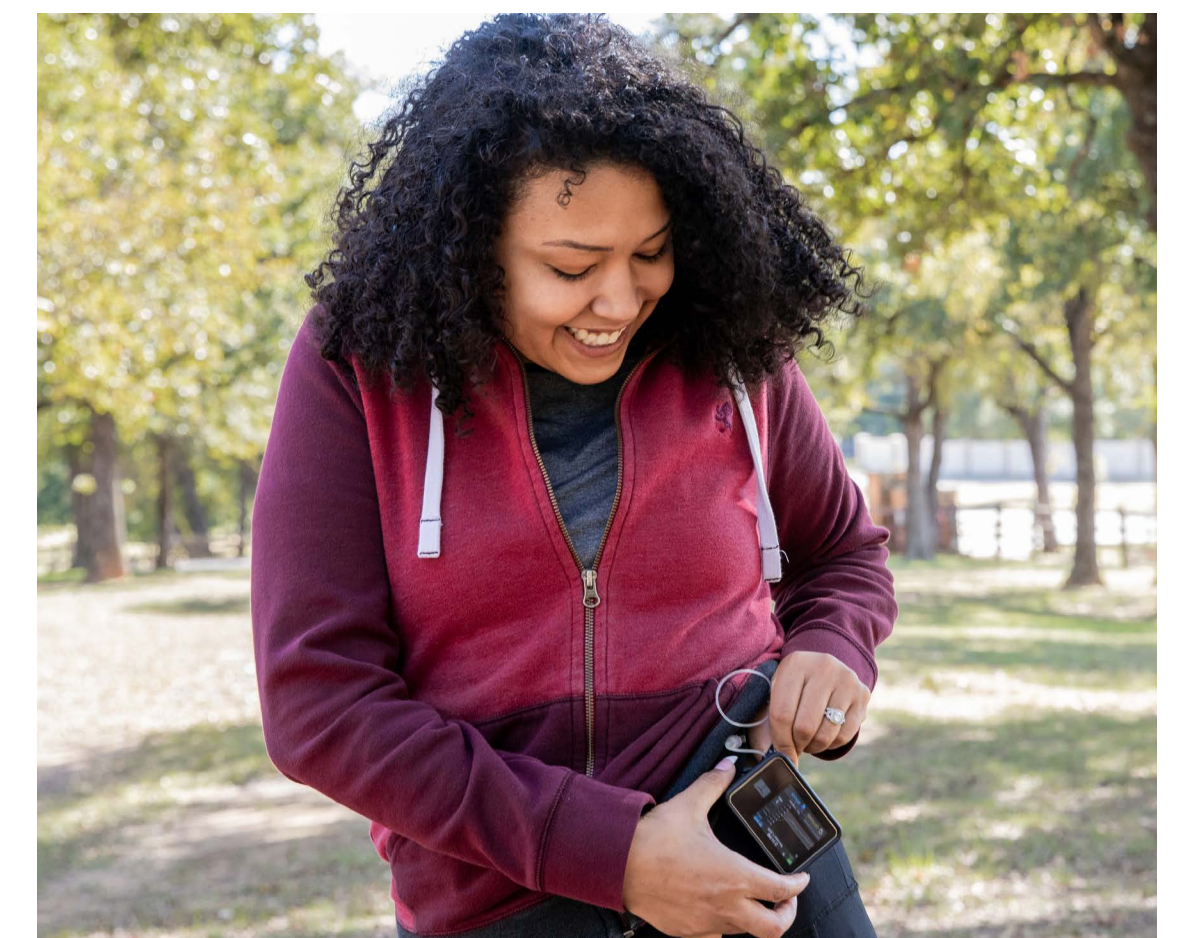
The regulations also require the manufacturer to have sufficient financial coverage for their potential liabilities in the event of claims for compensation for damage caused by their devices.

The first step in planning for implementation is to understand the scope of the activities that concern your organization and the medical devices that are involved.

Activities undertaken by distributors that make them responsible for obligations of the manufacturer should be considered. These include:

- making the device available under the name of the distributor;
- changing the intended purpose of the device; or
- modifying the device such that compliance with applicable requirements is affected.

Providing, including translating, information from the manufacturer or changing the outer packaging of the device to be suitable for a particular market are not considered to be modifications to the device that could affect compliance with the regulations. Distributors have to identify on the device or its packaging any of these activities that are performed and have a QMS that includes procedures that ensure that any translations are accurate and up to date.



The following are some key questions to be considered:

- What role(s) do you undertake within the supply chain? Do you act as manufacturer, authorized representative, importer, distributor or some combination thereof? Do you assemble procedure packs?
- Are you a manufacturer located outside the EU? If so, does the agreement with your authorized representative need updating to reflect new responsibilities? Who acts as the importer into the EU? What does the agreement with that importer currently cover and what changes will be needed to define the authority and responsibilities in the regulations?
- Do you distribute products from other manufacturers? If so, are your agreements with the manufacturer up-to-date and meet all the requirements of the Regulation(s)? Is the manufacturer on schedule in implementing their strategy to change the CE-marking from the Directive to the Regulation(s)?
- Do you use distributors in your supply chain? Do the agreements cover the roles and responsibilities foreseen in the regulations? Are you on schedule in any updating and finalization of new agreements?
- Do any of your distributors, including any local subsidiaries or affiliates, undertake activities that would make them responsible for obligations of the manufacturer? Do they understand their responsibilities and have the necessary procedures and processes in place?
- Do any of your distributors, including any local subsidiaries or affiliates, perform translation of information or repackaging of devices? If so, do they have appropriate procedures in place to make sure that translations are accurate and up to date?
- Do you have measures in place to provide sufficient financial coverage in respect of any potential liability for damage caused by your devices?



Product portfolio

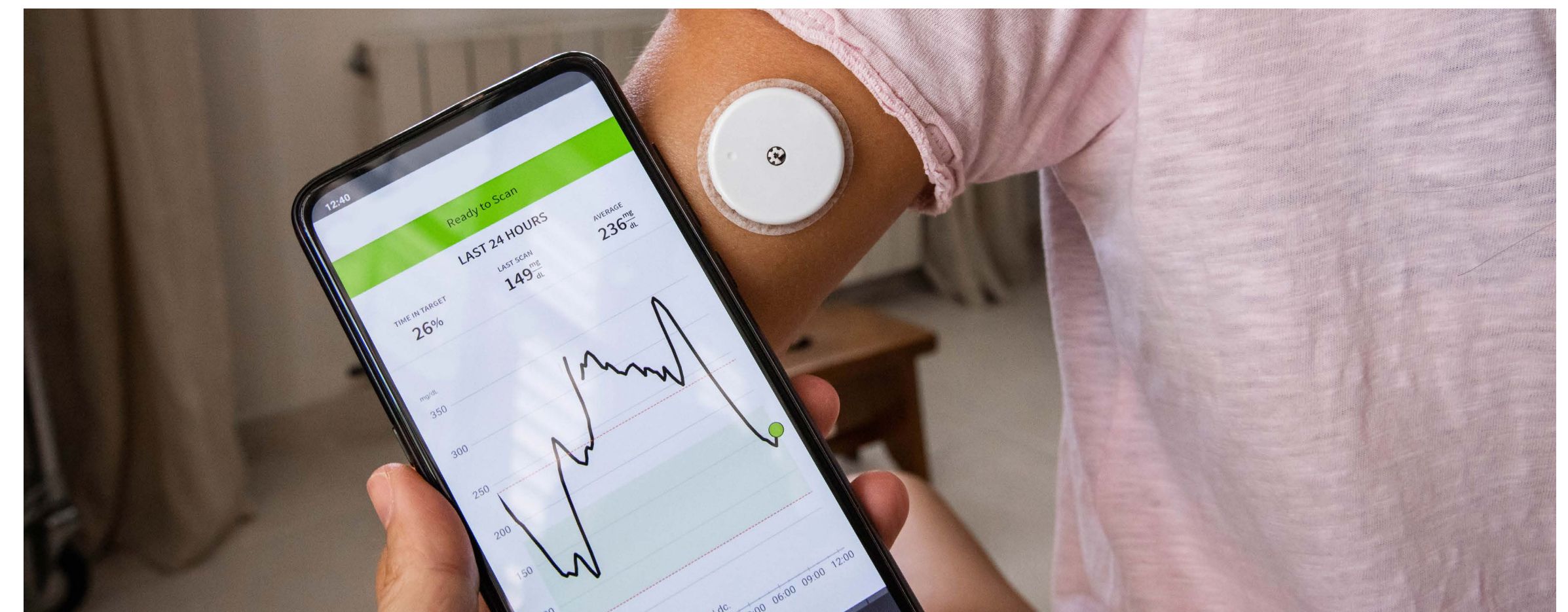
In order to CE-mark your devices against the regulations, all the requirements have to be met. There is no automatic acceptance of existing devices that are CE-marked against the Directives. Your portfolio of products needs to be reviewed against the new and revised requirements in order to determine the actions needed to change the CE-marking to the Regulation and the timing of that change. This includes products that are currently CE-marked under the Directives as well as those not currently requiring CE-marking because there are changes to the definition of a medical device that could affect your products. The changes to the definition of a medical device in the Medical Device Regulation mean that some products that were previously regulated under the Directive as accessories are now covered by the definition of a device, with a knock-on effect in bringing products that were previously outside the scope of the Directive being considered as accessories to what are now devices under the Regulation.

For example, the definition now explicitly includes products specifically intended for cleaning, disinfecting or sterilizing medical devices, where these were previously considered accessories; consequently, sterilization indicators that were previously outside the Directive can now be considered accessories to the sterilizing equipment and thus covered by the Regulation. However, the exclusion in the scope of the Regulation for products that contain or consist of living micro-organisms gives a situation where biological indicators for sterilization could be considered excluded from the Regulation but where chemical indicators for sterilization are considered as accessories. In addition, there is clarification that software in its own right, when intended to be used for medical purposes, is an active medical device, but software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being applications, are not devices.

In addition, certain devices for aesthetic purposes are bought under the Medical Devices Regulation. The specific devices affected are listed in Annex XVI of the Regulation. One of the challenges of addressing aesthetic devices that are not considered to have a medical purpose is the characterization of benefit versus risk. The Commission has adopted a common specification¹⁶ that address application of risk

management and clinical evaluation of safety to these products. The Regulation applies to aesthetic products from the date that the common specifications are adopted.

¹⁶ Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications in accordance with Regulation (EU) 2017/745.



A common specification is a document other than a standard that gives technical or clinical requirements providing a way to comply with the requirements of the Regulation. Common specifications have been introduced into the MDR but were previously an element of the IVD Directive, where they were called common technical specifications. In general, manufacturers are obliged to comply with common specifications unless they can justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent; for aesthetic devices, the applicable common specifications are mandatory. The status of harmonized standards that are listed in the Official Journal of the European Union in providing a voluntary means to achieve a presumption of conformity with certain regulatory requirements has not changed in the regulations from that in the Directives.

There are also changes in the classification rules that could affect your products under both the MDR and the IVDR. For Medical Devices, there are products for which the classification has increased or the oversight by the notified body has been heightened without an increase in classification. For example, surgical meshes, devices in contact with the spinal column (with some exceptions) and some substance-based devices have been increased in classification; additional notified body oversight is required for Class IIb implants and Class I reusable surgical instruments. For IVDs, a new classification system based on a set of rules has been introduced that will increase the classification for many products and the extent of notified body involvement.

The Medical Device Coordination Group (MDCG) was established in accordance with Article 105 of the MDR and Article 99 of the IVDR. They have prepared a number of guidance documents in collaboration with interested parties, including on borderline products and classification.^{17,18}

One of the key areas that you will need to review is in the clinical evidence that you have to support your device and whether that clinical evidence relies on demonstration of equivalence with a comparator device. You will have to be able to demonstrate that the device is equivalent to its comparator, based on scientific justification, concerning the following.

- Technical characteristics: device is similar in regard to design, specifications and properties, conditions of use, principles of operation and critical performance requirements.
- Biological characteristics: device uses the same materials, in contact with the same human tissues, and with similar release properties.
- Clinical characteristics: device has the same clinical application at the same site in the body, in a similar population, with similar performance and with the same kind of user.

There needs to be no significant difference in the clinical performance and safety of the device and the comparator, and you have to be able to demonstrate that you have access to the data on the comparator device in order to justify that claimed equivalence. This is likely to restrict the use of equivalence to devices from the same manufacturer, unless there is an agreement in place allowing access to the necessary information on the comparator device.

In June 2016, a revision of MedDev 2.7/1 Revision 4¹⁹ on clinical evaluation was issued. Although this is guidance on the Medical Devices Directive, it provides a preview of some of the expectations in the Medical Devices Regulation. However, MedDev 2.7/1 Revision 4 and the MDR diverge in some areas, so familiarity and knowledge of both – and, in particular, the differences between them – is important during the transition period. Planning for compliance with MedDev 2.7/1 Revision 4 is likely to form a step in a comprehensive plan to come into compliance with the Medical Devices Regulation and drive the timeline for some activities.

¹⁷ MDCG 2021-24, *Guidance on classification of medical devices*.

¹⁸ MDCG 2022 – 5, *Guidance on borderline between medical devices and medicinal products under Regulation (EU) 2017/745 on medical devices*.

¹⁹ MEDDEV 2.7/1 Revision 4 – June 2016, *Guidelines on Medical Devices – Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC*.



The MDCG have prepared a number of guidance documents on clinical evidence, clinical evaluation and clinical investigation, such as:

- *Guidance on sufficient clinical evidence for legacy devices*²⁰;
- *Guidance on clinical evaluation – Equivalence*²¹; and
- *Questions and answers regarding clinical investigations*²².

20 MDCG 2020-6, *Regulation (EU) 2017/745 – Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC – A guide for manufacturers and notified bodies April 2020.*

21 MDCG 2020-5, *Clinical Evaluation – Equivalence – A guide for manufacturers and notified bodies.*

22 MDCG 2021-6, *Regulation (EU) 2017/745 – Questions & Answers regarding clinical investigation.*

The following are some key questions to be included in the review:

- Are any of your products affected by the changes to the definition of a medical device? Do you have products that were previously outside the Directives but will become devices or accessories within the scope of the Regulation as a result of the changes in the definition of a device?
- Do you have any aesthetic products without a medical purpose listed in Annex XV of the Medical Devices Regulation? Are they within the scope of your quality management system and design and development procedures? Are you monitoring the development of common specifications that will apply to these products?
- What classes of devices are you concerned with?
- Are any of your products affected by the changes to classification rules? For instance, if you have products that have had their classification increased or are considered as Class IIb implants, do you understand the new requirements that will result? Do you have Class I reusable surgical instruments in your portfolio, and, if so, are you complying with the new requirements and prepared for the additional notified body oversight?
- Do you have the necessary clinical evidence to meet the requirements of the Medical Devices Regulation? Have you implemented the guidance in MedDev 2.7/1 Revision 4 on clinical evaluation or have a plan to do so? Does your clinical evidence rely on equivalence with another device, and, if so, are you able to meet the additional expectations for equivalence as defined in the current guidance and in a much more restrictive manner under the Regulation?
- Is your device considered a well-established technology under the Regulation? If so, do you have robust post-market data, collected and reviewed systematically under the Directive, to support CE-marking under the Regulation?
- Do you need to consider additional post-market clinical follow-up in order to gather information to support CE-marking under the Regulation?

- Do your devices contain substances that are carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B²³, or endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health²⁴ (hereafter referred to as hazardous substances)? Have you documented a justification for their use?
- What is the cycle of review for your Technical Documentation or Design Dossiers? When do you want to transition CE-marking for existing products to the Regulation? For which products will you renew CE-marking under the Directive during the transition period? What changes will be required to the supporting documentation in order to achieve this?
- Will your renewal cycle mean that you have some devices CE-marked under the Medical Devices Directives and others under the Medical Devices Regulation during the transition period? How will you manage your activities under the Directive and Regulation simultaneously? What impact will this have on your procedures and capacity?
- How will you prepare, review, approve and submit the summary of safety and clinical performance as is required for class III and implantable devices? How will you keep these up to date throughout the lifecycle of the device(s)?
- Do you have any products that are own brand labelled? If so, do you have access to all the information to meet the requirements as the virtual manufacturer of such products? Does the original equipment manufacturer have a strategy to support CE-marking to the Regulation? Does your agreement with the original equipment manufacturer need to be updated?
- Does transitioning your device to being CE-marked under the Regulation have sufficient return on investment to be viable from a business perspective?

23 Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

24 Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, authorization and Restriction of Chemicals (REACH) or those criteria that are relevant to human health of the criteria established in the delegated act adopted by the Commission pursuant article 5(3), first paragraph, of Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market of and use of biocidal products.



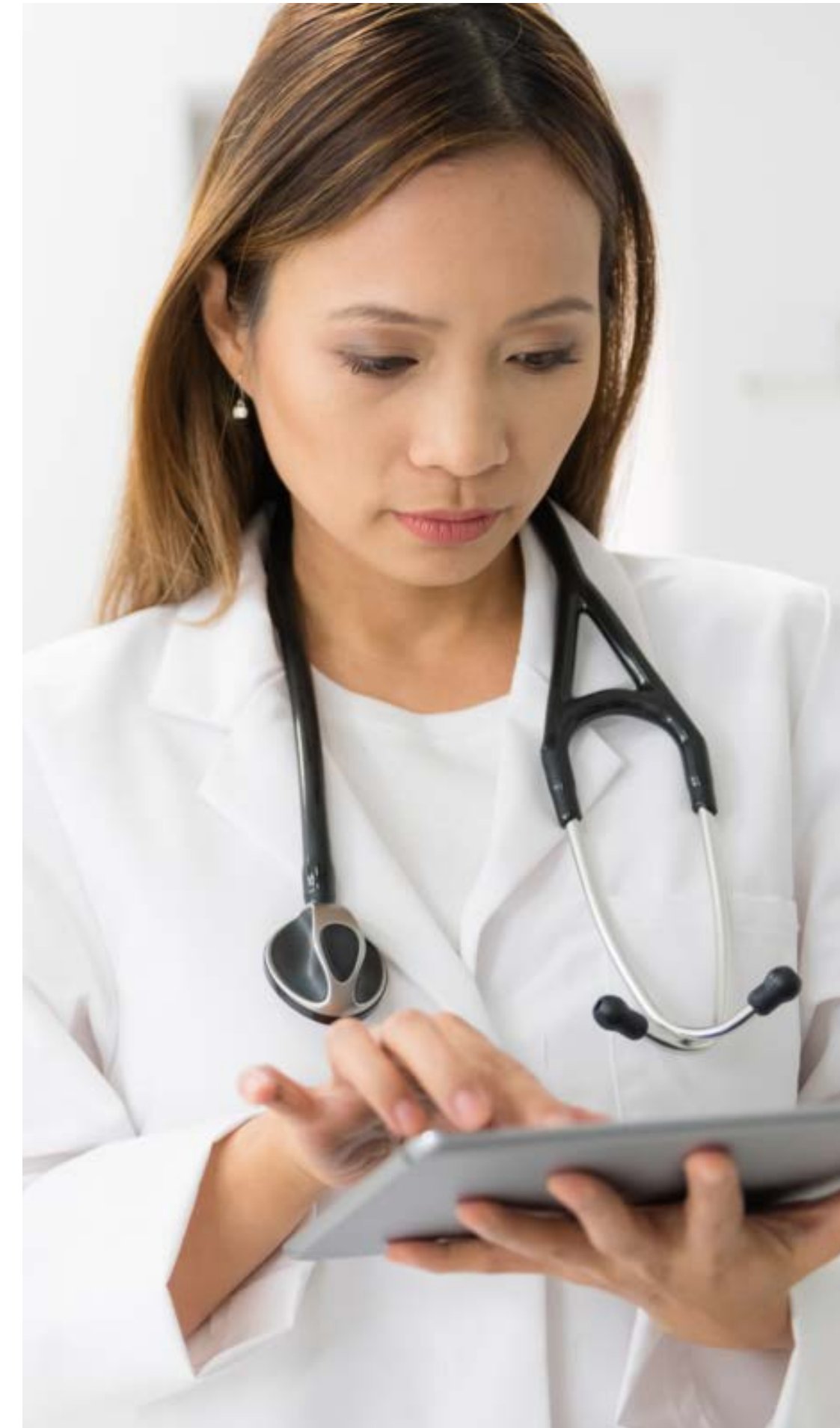
New product development

The requirements of the Regulation will inevitably lead to changes in your procedures for design and development. Design and development plans will need to be adjusted to:

- address the increased requirements for clinical evidence;
- avoid or justify the use of hazardous substances and keep up-to-date information on the substances that are categorized as such;
- generate recommendations on any post-market clinical follow-up that might be needed;
- produce the summary of safety and clinical performance for class III and implantable devices and make this publicly available;
- produce a summary of clinical investigation that is easily understandable by the intended user and make this publicly available; and
- ensure consistency between the risk management plans, determinations of risk and benefit, clinical evaluation reports, post-market surveillance plans and technical documentation.

The product in your research and development pipeline and their development plans need to be reviewed to assess the impact on your ability to launch these products, the effect on the development and launch timelines, and any additional needs for the development plan. The questions above for the current portfolio are also relevant to products in the development pipeline, in addition to the following.

- What is the launch timeline for products in the pipeline?
- Do you have any novel, class III implantable devices or class IIb devices intended to administer a medicinal substance? As these will be subject to the new procedures for clinical evaluation consultation (scrutiny procedures), how will this affect the development plan and timelines for approval?



- Do you conduct clinical investigations in the EU?
- Is your sponsor of a clinical investigation established in the European Union or is there a legal representative in the European Union responsible for ensuring compliance with the sponsor's obligations? Do you have a process to confirm that:
 - a. the device conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation; and
 - b. every precaution has been taken to protect the health and safety of the patient(s) taking part? Is this confirmation recorded?
- Does the cost of implementing changes to the design and development plan affect the return on investment and commercial viability of the design and development project?

Device changes

One of the provisos in the transitional arrangements for the regulations that allow for devices with valid certificates or declarations of conformity to the Directives to continue to be placed on the market is that there is no significant change to that device. Consequently, the procedure for design and development changes will need to consider whether any proposed changes to such devices are significant and, if so, the generation of evidence to transition the changed device to the MDR or IVDR. This is likely to affect the timelines and resources needed for the design and development change.

The following are some key questions.

- Does the procedure for design and development changes address the regulatory requirements associated with the change?
- Are the implications for legacy products placed on the market with certificates or declarations of conformity with the Directives identified and considered?
- If a change is proposed to a device placed on the market with certificates or declarations of conformity with the Directives, are the necessary resources assigned to transition the device to the Regulation and the effect on the project timelines taken into account?



Quality management system (QMS)

The regulations include requirements for the quality management system (QMS) that presents the QMS as the place where the regulatory requirements come together to be implemented systematically throughout the lifecycle of the device. EN ISO 13485:2016 includes direct reference to incorporating regulatory requirements in the QMS and is compatible with the requirements in the regulations.

Updating the QMS will be critical on the path to being able to CE-mark a device under the Regulation. Furthermore, the QMS will need to drive the changes that are needed in the organization's processes, including ensuring that:

- requirements of the Regulation are considered as an input to Management Review;
- changes to the QMS are planned to make sure that the integrity of the QMS, and the safety and performance of devices under the control of that QMS, are maintained;
- training on the requirements of the Regulation and new or modified procedures of the QMS is documented, delivered, recorded and shown to be effective; and
- internal audits are conducted to confirm the effective implementation of any new or revised procedures.

The QMS will need to define and document the roles and responsibility of the person responsible for regulatory compliance in the organization of the manufacturer and, where applicable, the authorized representative. The manufacturer has to have the person responsible for regulatory compliance available within their organization, unless they are recognized as a micro or small enterprise²⁵. The Regulation recognizes that, in larger organizations in particular, these responsibilities are likely to be split between different individuals in separate functions. In contrast, the authorized representative – and micro or small enterprises acting as the manufacturer – do not have to have the responsible person in their organization, but permanently and continuously at their disposal. The definition of these roles in the Regulation is likely to require changes in QMS documentation as well as the job descriptions for certain positions, possibly including the Management Representative, as well as agreements with external parties if these responsibilities are outsourced.

The defined responsibilities for the person responsible for regulatory compliance in the manufacturer are to ensure that:

- conformity of devices is checked in accordance with the QMS under which these devices are manufactured before a product is released;
- technical documentation and the declaration of conformity are drawn up and kept up to date;
- post-market surveillance obligations are met;
- reporting obligations for vigilance are fulfilled; and
- investigational devices conform to the general safety and performance requirements, apart from the aspects covered by the clinical investigation, and that every precaution has been taken to protect the health and safety of the patient(s).

²⁵ Defined in Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises.

The MDCG have prepared a guidance document on the person responsible for regulatory compliance.²⁶

Implementation of risk management is a crucial aspect in achieving compliance with the regulations, not only in design and development but throughout the lifecycle of the device. Requirements for risk management are detailed in the general safety and performance requirements (GSPRs) in Annex I of the regulations. A European amendment to EN ISO 14971²⁷ was published in December 2021. The amendment replaces the European Foreword and adds two new Annex Zs – designated ZA and ZB – which show the relationship between the clauses of the standard and the requirements of the MDR and IVDR. The Annex Zs point out that the manufacturer’s policy for establishing criteria for risk acceptability has to ensure that the criteria comply with the GSPRs.

EN ISO 14971:2019+A11:2021 has been listed in the Official Journal as a harmonized standard providing a presumption of conformity to the MDR²⁸ and IVDR²⁹ to the extent listed in the Annex Zs.

The plan for implementing the requirements of the Regulation will require documented procedures to be created, approved and implemented for all the new processes needed and for procedures for many existing processes to be revised. The plan will also need to include the provision of training on any new or revised procedures.

The following are some key questions.

- Is the scope of your organization appropriately documented in your Quality Manual? Does your documentation adequately reflect the authorities and responsibilities as defined in the Regulation?
- Does the scope of your QMS cover the types of devices concerned, taking account of changes in the definition of a device and the inclusion of aesthetic products in the Regulation?
- Do you have certification to EN ISO 13485?
- Do your risk management processes cover the lifecycle of the medical device? Have you assessed your procedures against the requirements of EN ISO 14971? Have you addressed any gaps between the requirements of EN ISO 14971 and the requirements of the regulations as identified in the Annex Zs to the standard?

- Have the consequences of the Regulation and the necessary resources been considered in Management Review? Are the outputs of that discussion recorded?
- Is your implementation plan documented and available as evidence of Quality Planning?
- Have personnel had the necessary training on the Regulation, as appropriate for their responsibilities? Are the personnel that undertake internal audits trained in the new requirements? What records are available of this training?
- How many new procedures will you need to create and how many existing procedures will you need to revise? What is the timing of the creation or amendment of these procedures?
- How will your document management system for approval, issue and training on new or revised procedures deal with the number of documents that have to be handled?

28 EU 2022/757 Commission Implementing Decision (EU) 2022/757 of 11 May 2022 amending Implementing Decision (EU) 2021/1182 as regards harmonized standards for quality management systems, sterilisation and application of risk management to medical devices.

29 EU 2022/729 Commission Implementing Decision (EU) 2022/729 of 11 May 2022 amending Implementing Decision (EU) 2021/1195 as regards harmonized standards for quality management systems and for application of risk management to medical devices.

26 MDCG 2019-7, *Guidance on Article 15 of the Medical Device Regulation (MDR) and in vitro Diagnostic Device Regulation (IVDR) regarding a ‘person responsible for regulatory compliance’ (PRRC)*.

27 EN ISO 14971:2019+A11:2021, *Medical devices — Application of risk management to medical devices*.

Technical documentation

The regulations define additional detail for the content of the Technical Documentation – often referred to as the Technical File – for each medical device or family and require that the information is presented in a clear, organized, readily searchable and unequivocal way. The regulations also reinforce the emphasis on the requirements driving a lifecycle approach to the management of the medical device with the routine updating of the Technical Documentation, including:

- in the light of information gathered during post-market surveillance;
- evolution in the state of the art; and
- development of changes to standards or common specifications used to support CE-marking.

The Technical Documentation includes the:

- device description and specification, including reference to previous and similar generations of the device;
- information supplied by the manufacturer on labels and accompanying documents, including any symbols used;
- design and manufacturing information;
- demonstration of conformity with general safety and performance requirements;
- risk management information and risk-benefit determination;
- product verification and validation information, including:
 - pre-clinical and clinical data; and
 - additional information in specific cases where a device:
 - incorporates a medicinal product;
 - is manufactured utilizing tissues or cells of human or animal origin, or their derivatives;
 - is composed of substances or combination of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body;

- contains hazardous substances;
- is placed on the market in a sterile or defined microbiological condition;
- is placed on the market with a measuring function; and/or
- is to be connected to other device(s) in order to operate as intended;
- technical documentation on PMS, including:
 - post-market surveillance plan; and
 - periodic safety update report for class II or class III devices or post-market surveillance report for class I devices;
- EU declaration of conformity.

The Technical Documentation needs to be controlled as QMS documentation. In large organizations, it is likely that the documentation will be generated by a variety of different functions depending on how the organization is structured – for example: Quality Assurance, Manufacturing, Supply Chain, Regulatory Affairs, R&D, Clinical/Medical, Safety – and the document management system(s) need to enable the Technical Documentation to be organized, up-to-date and readily searchable throughout the device lifecycle.

The following are some key questions:

- Does your document management process enable the Technical Documentation to be organized and readily searchable, and be kept up to date throughout the device lifecycle?
- What new documents do you need to include in your Technical Documentation?
- Do you have processes to monitor the adoption of new standards or common specifications, or changes to existing standards or common specifications? How do you assess the effect of such new or revised documents on your Technical Documentation?



Labelling

There are many implications for the information in labels and instructions for use within the regulations. Such information might appear on the device itself, on the packaging or in the instructions for use, and, in addition, if the manufacturer has a website, be made available and kept up to date on that website. Every label and instruction for use is likely to need to be changed to comply with the requirements. Implementing label changes can take some time and requires planning; it is likely that all the changes will not be able to be made at the same time, and that an overall strategy will be needed that includes a solution to have enough space on a label for all the necessary information.

Unique Device Identification (UDI) will have to be implemented. The timing for this implementation is on a longer timescale than the transition for the Regulation and is phased according to the classification of the medical device³⁰. While the UDI

requirements are similar to those in the USA, there are some differences in the classification of devices between the USA and the EU which might lead to the timescales for implementation diverging.

Patients will have to be provided with information on certain implants; this will have to be in an appropriate language and written to be readily understandable by a lay person. The information also needs to be kept up to date. The patient has to have rapid access to:

- warnings and precautions to be taken by the patient or a healthcare professional;
- information about the expected lifetime of the device and any necessary follow-up; and
- other information to assure a safe use of the device by the patient.

While this information is likely to be made available through a website, the patient also has to be provided with a physical card containing particular information, some of which will be batch specific:

- identification of the device: device name, model, serial number, batch code or lot number and UDI; and
- name, address and the URL of the website of the manufacturer.

The MDCG have prepared guidance documents on implant cards.^{31, 32}

The following are some key questions.

- Have you completed a gap assessment of the information required on the labels and in the instructions for use?
- Do you have enough space on your label and in your instructions for use to include the additional required information? If not, how could you accommodate for the additional information required?

- Are there recognized symbols in harmonized standards that you can use for some of the required information or will it need to be presented in multiple languages?
- Do you supply implants that require provision of an implant card? If so, what is your strategy to provide the implant card in an appropriate language?
- Are there additional labelling requirements that you need to meet for hazardous substances? Are you monitoring for additional information to be provided by the European Commission on these labelling requirements?
- When will the requirements for UDI apply to the classes of devices that you are concerned with? Do you have procedures to obtain the necessary UDI for other markets that you can adapt, or do you need to create these procedures?

30 Council of the European Union, Interinstitutional File: 2012/0266 (COD) Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, 27 June 2016, Article 97 paragraph 3 c & ca.

31 MDCG 2021-11, *Guidance on Implant Card – ‘Device types’*.

32 MDCG 2019-8 v2, *Guidance document Implant Card relating to the application of Article 18 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices*.

Post-market surveillance (PMS) and vigilance

The regulations contain significant changes in requirements in the post-market area, including PMS planning and implementation, vigilance reporting and handling field safety corrective actions. Devices that are placed on the market with valid certificates or declarations of conformity to the Directives are subject to the requirements for PMS and vigilance in the regulations.

There are enhanced requirements for PMS plans, including conducting active post-market clinical follow up (PMCF) when necessary, preparing periodic safety update reports (PSUR) for class II and class III devices and submitting or having these available for Notified Body Review at defined intervals depending on the device classification, and maintaining post-market surveillance reports (PMSRs) available for class I devices.

Regarding the requirements for vigilance, information previously contained in guidance has been included in the Regulation itself. The number of exemption rules that obviate the need to report events have been reduced. The timelines for reporting events that are considered serious public health threats or a death or unanticipated serious deterioration in health have remained unchanged at two and ten days respectively, but the timeline for reporting all other events has been decreased from 30 days to 15 days. This reduces the time available to determine whether an event meets the reporting criteria and could lead to submission of more follow-up reports to provide additional information. Taken together, these changes are likely to lead to an increase in the number of reports submitted.

When conducting a Field Safety Corrective Action, the manufacturer has to inform the Competent Authority before implementing the action, unless this would cause a delay with a consequent risk to health.



The following are some key questions.

- What changes need to be made to your current PMS plans to meet the requirements of the Medical Devices Regulation? Will you need to prepare a PMCF plan?
- How will the changes in timing and exclusion criteria for vigilance reporting effect the number of vigilance reports that you will have to make? Can your current process for investigating complaints reliably submit vigilance reports in a 15-day period? Do you have the resources to handle any foreseen increase in initial and follow-up reports?
- Do your procedures for implementing field safety corrective actions include informing the Competent Authority prior to implementation?
- What changes will you need to make to your procedures in order to prepare PSURs or PMSRs? Do you have the resources to prepare these reports and, when necessary, submit PSURs to your Notified Body for review?

EUDAMED

EUDAMED, the European medical devices database, is the IT system that will be the interface for registering economic operators and devices, obtaining a single registration number and communicating between the various parties under the Regulation, including submitting clinical investigation reports, vigilance reports and periodic safety surveillance reports. Certain parts of the information in EUDAMED will be publicly accessible. EUDAMED is introduced in Article 33 of the MDR and article 30 of the IVDR but is referenced in 50 articles in each Regulation. It is one of the cornerstones of the regulations.

The Commission Implementing Regulation (EU) 2021/2078³³ of 26 November 2021 lays down the detailed arrangements necessary for the setting up and maintenance of EUDAMED.

³³ Commission Implementing Regulation (EU) 2021/2078 of 26 November 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the European Database on Medical Devices (EUDAMED).

EUDAMED is structured around six interconnected modules and a public website:

01

Actors registration;

02

UDI/Devices registration;

03

Notified Bodies and Certificates;

04

Clinical Investigations and performance studies;

05

Vigilance and post-market surveillance; and

06

Market Surveillance.

The use of EUDAMED is not currently mandatory nor required. The mandatory use of the system will start when the entire EUDAMED system of all six modules has been declared fully functional following an independent audit and a Commission notice published in the Official Journal. Some modules are already available and can be used voluntarily. The status of current various modules is as follows.

- The module on Actor registration has been available for voluntary use from December 2020.
- The module on UDI/Devices registration has been available for voluntary use from October 2021.
- The module on Notified Bodies and Certificates has been available for voluntary use since October 2021, except for the mechanism for scrutiny and the clinical evaluation consultation procedure.
- The remaining modules on Vigilance, Market Surveillance and Clinical Investigation and Performance Studies are under development and will be released when the entire EUDAMED system (including all six modules) is declared fully functional.

The following are some key questions.

- Are you following the development of the EUDAMED database and the status of its implementation?
- Are you gaining experience by using the available modules voluntarily?
- Have you defined the roles and responsibilities within your organization to interact with the EUDAMED database?
- Do your systems have the capability to produce an output that will be compatible with the EUDAMED database? If not, do you have a plan to develop such an interface?
- Do you have the resources to input the necessary information into the EUDAMED database?

External Factors

There are a number of external factors that you will need to take into consideration as you develop your implementation plans.

The Regulation identifies more than 40 areas where additional detail had to be produced by the European Commission in the form of delegated and implementing acts. In addition, it is likely that a substantial body of guidance will be needed to ensure that the implementation is uniform.

In addition, the Regulation will place further responsibilities on your notified body, who will also be under heightened scrutiny from Competent Authorities. Notified bodies will need to be designated under the Regulation and the process of designation is coordinated at a European level. The process of designation has been slow but there are now a number of notified bodies recognized for the MDR, albeit less than were available under the Directives. The low number of notified bodies under the IVDR remains a concern, particularly with the number of manufacturers that will need a notified body for the first time under the IVDR.

The following are some key questions.

- Has your notified body been designated under the applicable regulation? If so, does the resulting scope of designation of the notified body include the class and type of your devices? Does your notified body's plan designation affect your product development plans and product lifecycle activities such as renewal of certificates?
- Have you discussed your implementation planning with your notified body? Do your timelines fit with their expectations and capacity?
- What has your notified body done to increase its capacity to deal with the additional responsibilities? Are there any limitations on your planning due to their capacity?
- What is your strategy if your notified body has not received designation or is reducing its scope under the regulations?
- Do you have a process to monitor the development and adoption of implementing acts and guidance documents issued by the European Commission?



Conclusion

Your understanding of the requirements of the MDR or IVDR is a key to your ability to develop an implementation plan for your specific situation in order to ensure continuing regulatory compliance and your ability to provide the European Union market with safe medical devices that perform as intended.

The recent proposed extension to the transition arrangement for the MDR requires the manufacturer to have put in place a QMS in accordance with the MDR by 26 May 2024. Furthermore, under the proposal, a formal application for conformity assessment is required by 26 May 2024 and a written agreement with a notified body has to be in place by 26 September 2024 in order to take advantage of the extended transition arrangements. These deadlines need to be considered in your transitional planning.

In order to develop your Regulatory Strategy for gaining a CE-Mark under the regulations and your detailed project plan, you need inputs on the role(s) of your organization under the Regulation, its size, the way that you are organized and managed, the types of devices for which you have regulatory accountability, and your strategic business intentions. Developing the sequence of

activities and the responsibilities for carrying them out will be important, and will involve:

- deciding on the date at which new products will start to be CE-marked against the Regulation for launch;
- modifying the procedures that govern design and development, and particularly the generation of clinical evidence, so that new products have the necessary information to demonstrate compliance when they are ready to launch;
- understanding the expiration of existing certificates and declarations of conformity, and when the first of the existing product portfolio needs to transition its CE-mark to the Regulation;
- identifying any additional clinical evidence that is needed to support the existing product portfolio and planning to generate this clinical evidence in time to transition the CE-marking;
- evaluating all changes to the labels and instructions for use, including applicable service manuals, and planning a labelling strategy, recognizing that there can be long lead times for the labelling and printing changes;
- addressing the changes to the QMS so that the changes are planned and implemented systematically, driven by quality planning processes, supported by management review and internal audit;
- updating the lifecycle processes to drive any changes needed to support CE-marking of the existing product portfolio under the Regulation;
- ensuring that your process for design and development changes can identify changes to legacy products that are on the market with certificates or declarations of conformity with the Directives (the process should allow for any changed device to be transitioned to the regulations smoothly);
- revising the procedures for post-market activities to meet the requirements for vigilance reporting and the creation of the needed reports of post-market surveillance, including the timing by which the first such report will need to be submitted to your notified body; and,
- monitoring the development of delegated and implementing acts and the publication of guidance on interpretation by the European Commission.

Given the magnitude of the changes involved, it is prudent to monitor progress on your implementation plans regularly to navigate the complexities and accommodate external factors outside your direct control.

Author

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