Frequently-Asked Questions (FAQs)

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The aim of the FAQ document is to answer some key questions on the new EU Medical Devices Regulation (MDR) 2017/745 and the anticipated impact on implementation activities and resources.

The New MDR

What are the key changes in the new MDR?

The new regulation outlines stricter regulatory requirements as well as enhanced transparency for medical devices marketed in the EU. Some of the key changes include:

- Product scope expansion: the definition of medical device broadened to include non-medical and cosmetic devices not previously regulated
- Reclassification of some devices to a higher risk class and a new classification for reusable surgical devices requiring notified body oversight
- More rigorous clinical evidence for class III and implantable medical devices
- Systematic clinical evaluation of Class IIa and Class IIb medical devices
- More stringent documentation
- Roles of Economic Operators
- Implementation of Unique Device Identification
- More rigorous surveillance by Notified Bodies
- Greater scrutiny of Notified Bodies
- No “grandfathering” provisions

What are the implications of the new MDR for medical device manufacturers?

The MDR brings significant changes affecting medical device manufacturers that place their products on the European market. Implementation of UDI, significant changes to technical files and the quality system, and the generation of additional clinical evidence for devices currently on the market are some of the biggest burdens manufacturers face. Pro-active approach, advanced preparation and early action are the key to ensuring a successful transition to the new requirements.

Transition Period

What is the transition period for the MDR?

The MDR entered into force on 25 May 2017 and has a transition period of three years. Some requirements of the Regulation apply earlier than this, e.g. those for Notified Bodies or the Medical Devices Coordination Group, some later, e.g. physical application of UDI on labels, or can only apply once EU systems are in place, such as the aspects of EUDAMED. Article 120 of the Regulation lists the transitional provisions and should be referred to for more detail.

Do certificates issued under the existing Directives remain valid after the Date of Application (DoA)?

Certificates generally remain valid until the end of the period indicated on the certificate, unless significant changes are introduced in the design or intended purpose of the device and unless the validity of the MDD

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certificate exceeds four years from the DoA. After 27 May 2024, certificates issued under the Directives become void. The validity of certificates issued under the Directives after the DoA is conditional to compliance with the provisions described in Article 120(3).

Can Directive-compliant devices be marketed after the end of the transition period?

Devices placed on the market by virtue of a valid Directive certificate may continue to be made available on the market or put into service until 27 May 2025 provided there are no significant changes in the design and intended purpose of the device. However, the requirements of the Regulations relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices replace those of the corresponding Directive requirements.

Medical devices that were placed on the market after the DoA by virtue of a valid Directive certificate issued before that date may be made available until 27 May 2025. After 27 May 2025, any of these devices that are still within the supply chain and that have not reached their final user as being ready for use will have to be removed from the supply chain.

Economic Operators

What is the role of the Authorised Representative under the MDR?

Authorised Representatives will take on more risk and liability under the new regulation. The EC Rep will be held jointly liable for defective medical devices if the manufacturer has not complied with its obligations under the Regulation and is not located in the EU. The general obligations of authorised representatives are described in Article 11 of the MDR.

What are the responsibilities of importers and distributors?

Importers and distributors need to actively assess the devices they place on the market and ensure that they comply with the Regulation and that the manufacturer has fulfilled its obligations. Additionally, importers need to establish their own processes regarding the compliance and be willing to refuse to import a non-compliant device. The general obligations of importers and distributors are described in MDR Article 13 and Article 14 respectively.

How does the new MDR affect the medical device supply chain?

The MDR import and distribution requirements for medical devices expand regulatory due diligence from legal manufacturer to importers and distributors. Each economic operator needs to verify regulatory compliance independently and generate its own records of compliance and be aware that they may be subject to unannounced audits.

The MDR changes should be carefully taken into consideration when revising current supply and distribution agreements and all parties of the agreement should cover the new obligations with a full understanding of all responsibilities.

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Unique Device Identification (UDI)

What level of packaging hierarchy is required to carry UDI?

UDI carrier is placed on the label of the device and on all higher levels of packaging, and the UDI-DI is unique at each level of device packaging. Shipping containers (logistics unit) are not subject to UDI requirements.

What is Basic UDI-DI and where should it be included?

Basic UDI-DI is intended to identify a product model, which is a base product design or specification from which particular product is derived. Examples include devices that are sold in different versions, e.g. different sizes or colours, but which are otherwise technically the same.

Basic UDI-DI is the main key for records in EUDAMED modules and is referenced in relevant certificates and declarations of conformity; it is not intended to appear on product labelling.

What is the timeline to become UDI compliant?

The deadline for assigning UDIs and including it in documentation, as well as registration of Economic Operators, is the Date of Application.

Registration of devices and submission of UDI core data elements to EUDAMED is due within 18 months from the DoA, provided EUDAMED achieves full functionality. However, at any time after the DoA, the full registration of devices remains a pre-condition for reporting of serious incidents or FSCAs in EUDAMED.

The obligation to affix the UDI on the labelling go into effect in stages based on risk class. For class III and implantable devices, the requirement applies from 26 May 2021, for class II devices from 26 May 2023 and for class I devices from 26 May 2025.

Reusable devices, that require cleaning, disinfection, sterilisation or refurbishing between patient uses, are required to carry permanent UDI carrier on the device itself. The UDI direct marking requirements apply from two years after the dates for labelling for the respective class of devices.

Before these dates there is no legal requirement for manufacturers to label their devices with UDIs, although some manufacturers may choose to do so.

What information is part of EUDAMED?

The new EUDAMED database will include information on UDIs, the registration of economic operators (except for distributors) and of devices, certificates, clinical and performance investigations, post-market surveillance, vigilance and market surveillance.

The database will be used to report incidents, as a platform for authorities to cooperate and exchange information and will facilitate access to the regulatory documentation through the UDI.

Do Economic Operators have UDI obligations?

Yes, Economic Operators are required to verify that a UDI is assigned, the device is labelled in accordance with the Regulation and registered in EUDAMED.

Additionally, the Economic Operators are required to store UDI records (preferably electronically) for class III implantable devices and specific device categories determined by the Commission.

MDR Transitional Provisions

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! **The QMS needs to be MDR-ready on the Date of Application**

! **At any time after the DoA, the full registration of devices remains a pre-condition for vigilance reporting in EUDAMED**

! **No scope extensions and substantial changes of Directive certificates**

Practical Considerations

With the clock ticking toward 2020, MDR transition should be a high-priority for device companies currently marketing products, or planning to market products in the EU. Compliance will require an enterprise-wide approach, pulling together a cross-functional governance and program team.

Possible Timing Strategy	Consider if:
Get MDR-certified as soon as possible	Current scope includes self-certified or non-medical devices that will be NB-certified under the MDR; sufficient clinicial evidence is in place; changes to design or intended purpose are expected to be implemented in the next few years; new device is being introduced.
Get MDR-certified in the 'Second Wave'	New device is being introduced between 2020 and 2022; sufficient clinical evidence is in place; current scope falls under MDD Annex IV; your Notified Body is expected to remain active
Remain certified under the MDD until the end of the sift transition period	No design changes are expected to be made in the next few years; more time is needed to gather clinical data for current devices; classification of current scope is not changing. **End of the soft transition period will be a high workload for Notified Bodies and may result in delays in certification!**

Questions? Contact us at compliance@healthlinkeurope.com