Kennedy Van der Laan

The art of capturing the essence

Factsheet

Regulation EU 2017/745 on Medical Devices (MDR) and Regulation EU 2017/746 on *In Vitro* Diagnostic Medical Devices (IVDR)[1]

On 26 May 2020 the Medical Devices Regulation (MDR) will enter into force, with the *In Vitro* Diagnostic Medical Devices Regulation (IVDR) to follow on 26 May 2022.

Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2020 and *In Vitro* Diagnostic medical devise placed on the market pursuant to Directive 98/79/EC prior to 26 May 2022 may continue to be made available on the market or put into service until 27 May 2025 only.

In order for manufacturers, authorised representatives, importers, distributors and health institutions to be able to prepare for the new MDR and IVDR, Kennedy Van der Laan prepared an overview of the requirements of these upcoming regulations.

The MDR and IVDR show much similarity. Therefore, we decided to discuss the MDR and IVDR jointly.

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Factsheet summary

Manufacturers and authorised representatives:

- Changes will be made to the risk classification of medical devices and an introduction is made of a risk classification for in vitro diagnostics (more devices will fall under a higher risk class).
- New and additional requirements are put in place with regards to clinical investigation and clinical evaluation. This means more obligations for all kinds of high risk medical devices, before market access can be obtained.
- The new regulation introduces an extended scope of the MDR (more devices fall under the MDR).
- New general safety and performance requirements are presented.
- Obligation is introduced to place a unique identification code (UDI) on each medical device.
- Registration of all medical devices in Eudamed is a new requirement.
- New obligation to have a post-market surveillance system as an integral part of the quality management system.
- New obligation to provide sufficient financial coverage for potential liability for damage caused by defective products (under Directive 85/374/EEC).
- The MDR introduces an Annual Periodic Safety Update Report.
- Obligations are introduced to report all serious incidents (reported to the manufacturer by – for example – healthcare professionals).

Distributors and importers:

- Importers and distributors are (inter alia) obliged to verify that CE marking and EU declaration of conformity for each device has been drawn up, the device is labelled in accordance with the MDR and accompanied by the required instructions for use and a UDI has been assigned by the manufacturer.
- Importers should indicate on the packaging of each device their name, registered trade name or registered trade mark, their registered place of business and the physical address at which they can be contacted and located.
- If an importer or distributor believes that a device is not in conformity with the requirements of the MDR or IVDR, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer. Where the importer or distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.

Health institutions:

- New and broad definition of health institutions introduced.
- Health institutions should store and keep (preferably electronically) the UDI of implantable devices.
- Obligation introduced to provide an implant card to all patients with implantable devices.
- The MDR sets new preconditions for devices manufactured and used within health institutions.

Factsheet

Regulation EU 2017/745 on Medical Devices (MDR) and Regulation EU 2017/746 on *In Vitro* Diagnostic Medical Devices (IVDR)

General:

- The MDR and IVDR replace the current directives on medical devices and in vitro diagnostic medical devices (90/385/EEG, 93/42/EEG, 98/79/EG and Decision 2010/227/EU).
- The MDR and IVDR have direct external effect in all Member States. Some provisions will have to be elaborated further in national legislation. Therefore, in the Netherlands the current Medical Devices Act (Wet Medische Hulpmiddelen), Decision Medical Devices (Besluit Medische Hulpmiddelen), Decision in vitro diagnostic medical devices (Besluit in vitro diagnostica), Decision active implantable devices (Besluit actieve implantaten) and Medical Research Human Subjects Act (Wet Medisch-Wetenschappelijk Onderzoek met Mensen) will lapse or will be revised.
- The European Commission aims for a coordinated and harmonized implementation of the MDR and on its initiative started the Medical Device Coordination Group (MDCG).
- Requirements for Notified Bodies[2] will become stricter, as well as the regulatory control on Notified Bodies.
- Increasing control and monitoring by the competent authorities of each of the Member States.
- The MDR assigns new requirements to the manufacturer with regards to quality control throughout the life cycle of a medical devise.

Market access:

- The MDR makes some important changes to the classification regime for medical devices. Many devices will fall under a higher risk class following the MDR (see annex VIII of the MDR).
    - The changes are of importance, especially in relation to medical devices that use software or nanomaterials or are active implantable medical devices, or active therapeutic medical devices.
    - The definition of ‘software’ will change under the MDR. Manufacturers should carefully assess if the software they use, falls under the new defined term. Due to the changed risk classes, more software for therapeutic and diagnostic purposes will fall under a higher risk class.
    - For devices that are composed of substances or of a combination of substances that are absorbed by or locally dispersed in the human body, new specific classification rules are adopted. For this class of devices, a Notified Body will need to seek advice of the local medicine agency or the European Medicine Agency, in the process of granting market access.
- The scope of the MDR is extended compared to the current MDD. The MDR will also apply to devices comparable to medical devices – based on similar technology as

[2] The private entity responsible for the conformity assessment of the device, as appointed by the competent authority of a Member Sate.

analogous devices with a medical purpose - such as contact lenses and invasive laser devices (annex XVI MDR). The European Commission will adopt common specifications for these products as well as special requirements.

- The MDR sets new general safety and performance requirements, such as for labelling, technical documentation and quality management system.
- The MDR sets higher requirements for clinical investigation so that data generated in clinical investigations are more reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.
- MDR and IVDR place a higher relevance as to pre- and post market data with regards to clinical evaluation and clinical research.
- The manufacturer should perform a clinical evaluation, before a medical device may be brought onto the market.
- The manufacturer should appoint someone internally in its organization responsible for meeting the lawful requirements of the MDR.
- If the manufacturer is located outside the European Union, the manufacturer should appoint an authorised representative, serving as their contact person established in the EU, who is jointly and severally liable for defective products (Directive 85/374/EEC) with the importer and manufacturer.
- Manufacturers should place a unique identification code (UDI) on each of their medical devices, except custom made devices. This should improve the traceability of medical devices as well as that it should significantly enhance the effectiveness of the post-market safety-related activities for devices, which is owing to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities.
- All medical devices and all economic operators[3] should be registered in the Eudamed-database, making information on medical devices accessible for all economic operators as well as patients and healthcare professionals.

Specific rules for market access of *in vitro* diagnostic medical devices:

- The IVDR also introduces a risk classification for all *in vitro* diagnostic medical devices (instead of only a list of high risk products, as before). More products will have to be assessed by a Notified Body. Manufacturers of *in vitro* diagnostic medical devices will need to provide clinical evidence, like manufacturers of other medical devices.
- The IVDR introduces a new consulting procedure for companion diagnostics (devices which are essential for the safe and effective use of a corresponding medicinal product, for example for selecting or excluding patient groups for treatment on the basis of their biological characteristics).
- With regards to Class D *In vitro* diagnostic medical devices (the highest risk class), the Notified Body performing the conformity assessment shall request one of the EU reference laboratories to verify by laboratory testing the performance claimed by the manufacturer and the compliance of the device with the applicable common specifications (CS).

Market access for high risk medical devices and *in vitro* diagnostic medical devices:

- All medical devices in a risk class higher than Class I should be assessed by a Notified Body. In that case, the manufacturer will have to provide more clinical evidence

[3] Meaning a manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3) of the MDR;

in order to meet the requirements of the conformity assessment.

- All active implantable medical devices and accessories for such devices are Class III devices (highest risk category).
- In addition to the regular conformity assessment, a special additional procedure should follow for Class III implantable devices, and Class IIb active devices intended to administer and/or remove a medicinal product. The manufacturer will in that case be obliged to request expert panels to scrutinise their clinical evaluation assessment report. Competent authorities should be informed about devices that have been granted a certificate following a conformity assessment procedure involving an expert panel.

Post-market surveillance and vigilance:

- For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system.
- The clinical evaluation and its documentation shall be updated throughout the life cycle of the device concerned with clinical data obtained from the implementation of the manufacturer's post-market clinical follow up ('*PMCF*') and post-market surveillance plan.
- The manufacturer also needs to adopt a risk management system that should be carefully aligned with and reflected in the clinical evaluation for the device, including the clinical risks to be addressed as part of clinical investigations, clinical evaluation and post-market clinical follow up. The risk management and clinical evaluation processes should be inter-dependent and should be regularly updated.
- The manufacturer should provide sufficient financial coverage in respect of their potential liability for damage caused by defective products (under Directive 85/374/EEC).
- The manufacturer should annually draw up a Periodic Safety Update Report.
- All serious incidents and field safety corrective actions should be reported in Eudamed.
- Manufacturers should, upon request by a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned. The competent authorities may take all appropriate measures to prohibit or restrict the devices being made available on its national market, withdraw from the market or recall until the manufacturer cooperates or provides complete and correct information. The authority to impose an administrative fine is to be set out under national law (in the Netherlands changes will be made to the *Wet op de Medische Hulpmiddelen*).
- The competent authority may, upon request, facilitate the provision of the information and documentation provided to the competent authority by the manufacturer to the potentially injured patient or user and the patient's or user's health insurance company or other third parties affected by the damage caused to the patient or user.

Obligations of importers and distributors:

- Importers need to verify, before placing a device on the market, that (a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up; (b) a manufacturer is identified and an authorised representative has been designated by the manufacturer; (c) the device is labelled in accordance

with the MDR and accompanied by the required instructions for use; (d) where applicable, a UDI has been assigned by the manufacturer.

- Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.
- Distributors need to verify, before making a device available on the market, that (a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up; (b) the device is accompanied by the information to be supplied by the manufacturer; (c) for imported devices, the importer has complied with the relevant requirements set out above; (d) that, where applicable, a UDI has been assigned by the manufacturer.
- In order to meet the above obligations, the importer and distributor may apply a sampling method that is representative of the devices supplied by that distributor.
- Where a distributor or importer considers or has reason to believe that a device is not in conformity with the requirements of the MDR or IVDR, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative (and in case of the distributor, the importer). Where the importer or distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established. These obligations are under increased control and monitoring by the national competent authorities, with the possibility to impose an administrative fine under National law.

Health institutions:

- The MDR introduces a new and broad definition of a health institution as '*an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health'*. Not only health institutions, but also (for example) laboratories and public health institutions, fall under this broad definition.
- Health institutions should store and keep (preferably electronically) the UDI of implantable devices.
- Health institutions should provide an implant card, that is to be provided by the manufacturer, to each patient with an implantable device, making available in a comprehensible way all relevant information about the implant given to the patient, including any necessary health risk warnings or precautions to be taken. For example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.
- The MDR sets new preconditions for devices manufactured and used within health institutions, such as that:
    - the device shall meet the general safety and performance requirements set out in Annex I;
    - manufacturing and use of the devices occur under appropriate quality management systems;
    - the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use and makes certain information publicly available; and
    - the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market.
- Reprocessing and further use of single-use devices may only take place where permitted by national law.
- Patients and healthcare professionals will gain access to the European database with in formation on medical devices (EUDAMED).