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MDR Advisory Desk for healthcare institutions that manufacture, adjust and/or use medical devices

On May 25th, the new Medical Device Regulation (hereinafter: “MDR”) has entered into force. The MDR replaces the present Medical Device Directive (hereinafter: “MDD”). As of 26 May 2021 the MDR actually applies, which means that manufacturers of medical devices must comply with the new rules as of this date. In a number of situations, an exception applies to manufacturers of medical devices who already comply with the MDD: in these specific situations, the devices can be used for a longer period of time under the conditions of the MDD. Until 2025, these special transitional provisions apply.

What does this mean for your organization? Do all medical devices remain available? What happens with in-house manufactured medical devices? Do healthcare professionals need to take any new requirements into account?

INTRODUCTION MDR

(Digital) innovations in healthcare can increase quality and patient satisfaction and play a role in reducing the costs. A precondition is of course that these innovations meet the high standards of safety and quality for the best possible health of the patient.

The MDR aims to increase patient safety and ensure that innovative medical devices remain available to patients. The MDR therefore contains rules on market access, transparency in the healthcare market and on the traceability of medical devices. The MDR also tightens the rules for certain products, including software.

What does this mean for your healthcare institution?

As a result of the new rules, it is possible that devices that are being used within your organization, must be recertified and therefore may not be available. It is recommended to contact your suppliers to make sure you can identify any inconvenience. Besides, you should discuss relevant processes with your suppliers, such as the manufacturer’s post market surveillance plan and your organizations role within this process.

In addition, a number of new requirements apply to healthcare institutions. Depending on the role of the healthcare institution, the requirements for the healthcare institution can be determined. This role, on its turn, depends on the types of medical devices being used within the healthcare institution. Rules on clinical research and performance studies, implants, software, single use medical devices and the European EUDAMED database must also be taken into account. New rules regarding these topics can directly impact your organization.

We can distinct three types of medical devices used within a healthcare institution:

procured	adjusted	manufactured
All medical devices that have been procured by a healthcare institution and used following purpose as intended by the manufacturer.	All (partially) procured medical devices which have been adjusted within the healthcare institution or are being used outside the intended purpose.	All medical devices that have been manufactured in-house, possibly using parts from suppliers.

A selection of our services:

Memorandum of applicability

Do you want to know whether your solution falls within the scope of the MDR? Or do you want an inventory of the devices that are used within your organization, and to which class they should be assigned?

We can support you with writing down the relevant facts and intended purpose of your product and argue whether it could be considered a medical device and, if so, to which class it could be assigned.

Roadmap to Compliance

Within your organization, you want to be inhibited as little as possible by issues related to compliance, both during the development of inhouse manufactured devices and regarding the rest of your services.

By means of a roadmap to compliance, we can provide you with an overview of all the requirements that follow from the MDR and other relevant applicable standards. We can carry out a practical translation in order for you to comply with all applicable rules in the simplest and most efficient way possible. You can continue to use this dynamic document to remain compliant.

Gap Assessment

We can support you by mapping out which medical devices you use in-house, what your processes and procedures currently look like and to what extent this meets the requirements set by (among other things) the MDR.

After completing the assessment, you can get started with the documents supplied by us: an assessment framework to complement yourself, a report of the assessment carried out and a practical guidance.

Support

The MDR calls for renewed processes and awareness. For example, under the MDR, healthcare providers are obliged to make the implant information and the implant card available to patients who have received an implant. Healthcare professionals also have obligations with regard to the Unique Device Identification System ("UDI"). They must store and keep the UDI of the class III implantable devices they have supplied.

We can support you during the preparation, implementation and execution of these rules and procedures. We can facilitate you throughout the entire compliance transition on ad hoc basis.

For more information, visit our website https://www2.deloitte.com/nl/nl/pages/life-sciences-and-healthcare/topics/intellectual-property-ip-and-it.html or contact us:

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