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EU Medical Device Regulation

On May 25th, the new Medical Device Regulation (hereinafter: "MDR") has entered into force. The MDR replaces the present Medical Device Directive (hereinafter: "MDD"). In principle, the transition period runs until May 26th, 2020, which brings that medical devices must comply with the new rules on this date. In a number of situations, an exception applies to medical devices which 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.

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

Introduction MDR

The MDR strengthens the market access system, increases transparency in the healthcare market, improves the traceability of medical devices and tightens rules for certain products, including software.

It is of great importance for patients safety that manufacturers, importers, distributors and healthcare institutions meet the requirements that apply to them, to ensure that all medical devices are safe.

What does this mean for your heathcare institution?

As a result of the new rules, it's possible that devices that are being used within the healthcare institution, must be re-certified and . Devices that are being used within the healthcare institution could possibly be (temporarily) unavailable. It is recommended to contact your suppliers to make sure you can identify any inconvenience in time. Besides, you should discuss relevant processes with your suppliers, such as the manufacturer's post market surveillance plan and your institution's role within this process.

Moreover, a number of new requirements will be applicable for healthcare institutions. It depends on the role of the healthcare institution within the supply chain of a medical device, which requirements are applicable. This role, on its turn, depends on the types of medical devices being used within the healthcare institution. But rules on clinical research and performance studies, implants, software, single use devices and the European EUDAMED database should also be taken into account. New rules regarding these topics can directly impact you healthcare institution's organization.

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

procured

All medical devices that have been procured by a healthcare institution and used following purpose as intended by the manufacturer.

adjusted

All (partially) procured medical devices which have been adjusted within the healthcare institution or are being used outside the intended purpose.

manufactured

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 using related to compliance, both during the development of in-house manufactured devices and regarding the rest of your services.

We can provide you with an overview of all applicable laws and regulations for your organization by means of a roadmap to compliance. 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 for the long haul.

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

A number of things should be arranged within your organization. For example, a number of processes must probably be renewed and employees must be informed on the new rules and procedures. For example, under the Regulation, healthcare provides are given a few specific obligations with regard to the implant card and EUDAMED.

We can support you during the preparation, implementation and execution of these rules and procedures. We can facilitate you if necessary, so that you are ready for the Medical Device Regulation as quickly as possible.

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