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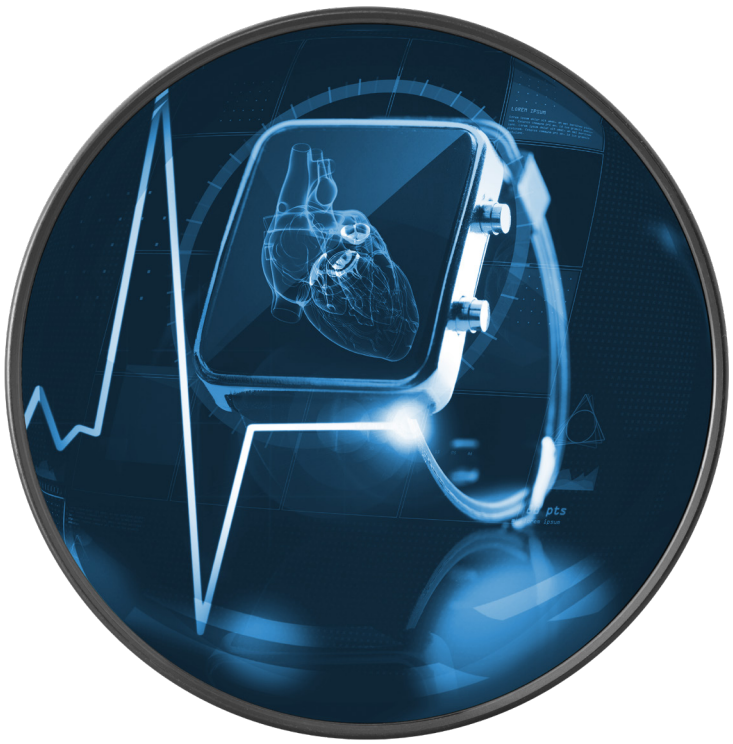

EU Medical Device Regulation

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 products? Will your product be qualified as a medical device under the Regulation? To which risk class will your software application be assigned? What steps should you take to obtain a CE mark (in time)?

Medical devices

Any **product** and **software** intended by the manufacturer to be used for human beings for one or more of the following medical purposes:

1. diagnosis, prevention, prognosis, monitoring, prediction, treatment or alleviation of disease,
2. diagnosis, monitoring, treatment, alleviation or compensation of injury or disability,
3. investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
4. providing information by in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

What does this mean for your organization?

As a manufacturer of a medical device, you must meet the requirements of the MDR in time. You should obtain a CE mark before you may access the market to sell your product. This means that you should (re)assess your product under the new classification system and in some cases (from class IIa) involve a notified body in the process to obtain a CE mark.

There are new rules for the requirements that a manufacturer must meet, for example with regard to general safety and performance requirements, obligations regarding registration and clinical evaluations. Every manufacturer must assign a person who is responsible for compliance with the regulations and should be able to prove that they have sufficient financial coverage in the event of liability for a defective product. Measures must be taken to prevent incidents and damage, but also to report occurring incidents and resolve them as quickly as possible.

Class I
Low risk

Class IIa
Average risk

Class IIb
Medium risk

Class III
High risk

The MDR introduces new rules for risk classification, for example for software:
Software intended to provide information which is used to take decisions with diagnostic or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person's state of health, in which case it is class III; or
- a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb. All other software is classified as class I.

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

Depending on the risk classification of your device, you should take into account a number of requirements. What are the action points within this area of the MDR for your organization?

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.

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. Your organization should be set up according to the new standards and employees must act according to these new standards.

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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