



On 25 May 2017, the new Medical Devices 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 products? Will your product be qualified as a medical device under the MDR? To which risk class will your software application be assigned? What steps should you take to obtain a CE mark (in time)?

MEDICAL DEVICES

What is a medical device?

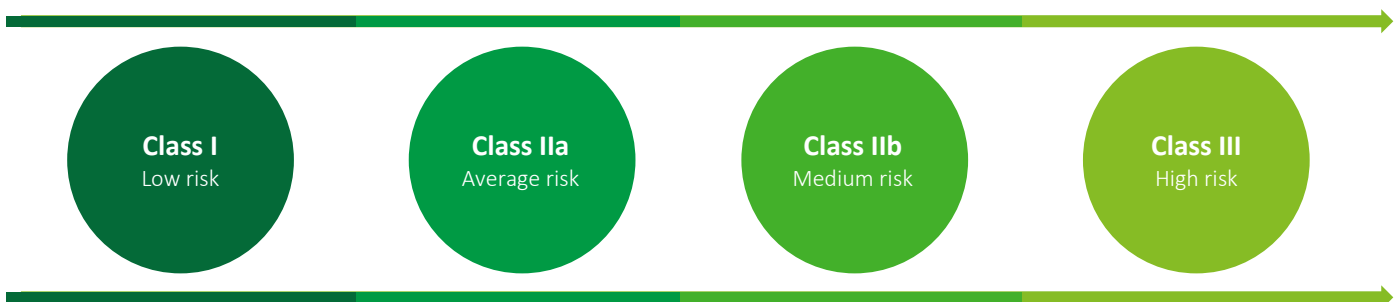
Any product and software intended by the manufacturer to be used for human beings for one or more of the following medical purposes:

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. You should obtain a CE mark before your medical device is placed on the market. 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.

The MDR introduces new rules for manufacturers, 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.



The MDR introduces new rules for risk classification, for example for software:

Software which drives a device or influences the use of a device 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:

1. death or an irreversible deterioration of a person's state of health, in which case it is class III; or
2. 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. If the software is independent of any other device, it shall be classified in its own right.

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

The MDR calls for renewed processes and awareness. Your organization should be set up according to 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 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:



Maaïke van Velzen

Partner Deloitte Legal
mvanvelzen@deloitte.nl
+31 (0)6 29 64 08 12
+31 (0)88 288 83 74



Frans Breuer

Senior Manager Deloitte Legal
FrBreuer@deloitte.nl
+31 (0)6 83 33 04 69
+31 (0)88 288 87 24

Deloitte.

Legal

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited ("DTTL"), its global network of member firms, and their related entities. DTTL (also referred to as "Deloitte Global") and each of its member firms are legally separate and independent entities. DTTL does not provide services to clients. Please see www.deloitte.nl/about to learn more.

Deloitte is a leading global provider of audit and assurance, consulting, financial advisory, risk advisory, tax and related services. Our network of member firms in more than 150 countries serves four out of five Fortune Global 500 companies. Learn how Deloitte's approximately 264,000 people make an impact that matters at www.deloitte.nl.

This communication contains general information only, and none of Deloitte Touche Tohmatsu Limited, its member firms, or their related entities (collectively, the "Deloitte network") is, by means of this communication, rendering professional advice or services.

Before making any decision or taking any action that may affect your finances or your business, you should consult a qualified professional adviser. No entity in the Deloitte network shall be responsible for any loss whatsoever sustained by any person who relies on this communication.

2021 Deloitte The Netherlands