Transparency, safety and higher quality with the MDR

seca.com/mdr

The MDR FAQ at a glance

This is an interactive document. Click on the relevant chapter to access it directly.

You can get back to the Overview by clicking the Homepage button.

01. What is the background of the MDR? Why was it adopted?

The Medical Device Regulation (EU) 2017/745 concerning medical devices, in short MDR - is a regulation on EU level and replaces the Medical Device Directive 93/42/EWG concerning medical devices, in short MDD. The **MDD** was an **EU directive** that needed to be transposed into national law. The **MDR** is a **regulation** and is binding EU-wide.

After several scandals caused by unsafe medical devices the European Union is seeking to improve patient safety with the new MDR. Therefore, along with the MDR,

+ stricter procedures regarding conformity assessment,
+ ongoing monitoring after market introduction,
+ the obligation of the manufacturers to collect data concerning clinical safety,
+ a uniform product labeling system for the traceability of products (UDI, also see question 16)
+ the creation of a European databank for medical devices (EUDAMED, see question 17) were introduced.

02. What does the MDR mean for users?

As operators of medical devices, hospitals and doctors’ practices are responsible for these meeting the current European requirements, and that the servicing of the medical devices is carried out in a MDR compliant manner. (To see from when it applies see infographic under point 3.)

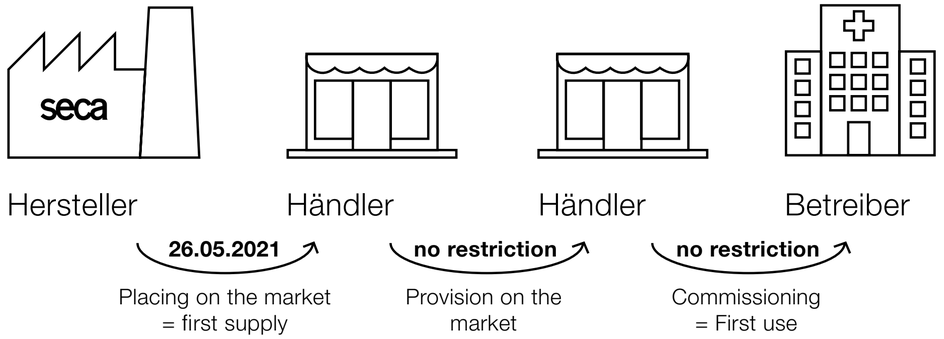
03. From when does the MDR apply and from when is it?

MDR came into force on the 26th May 2017 with a three-year transition period for implementing the new requirements. Due to COVID-19, and as it was to be expected, many manufacturers could not meet the transition deadline resulting in a one-year extension to assist in meeting the deadline. Moving forward, from 26 May 2021 only MDR compliant medical devices can be used. However, this deadline only applies to Class I medical devices. For medical devices of Class Im and IIb, the transition periods have been extended until 31.12.2028 according to EU Regulation (EU) 2023-607.

After these deadlines

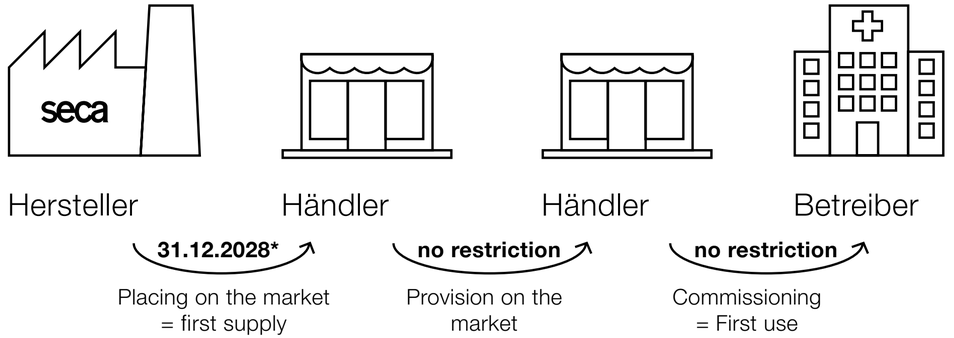
+ After the expiration of this period, manufacturers are no longer permitted to put the relevant products into circulation.
+ For making medical devices available on the market by distributors and the putting into operation of medical devices by operators, there are no longer any restrictions according to EU Regulation (EU) 2023-607

Medical devices of Class I



Transition periods for placing on the market and making available on the market and putting into operation. After the transition period only MDR compliant products can placed on the market, made available or put into operation.

Medical devices of Class IIb,IIa, Im, Is



*For this transition period, the following additional requirements must be met:
-Compliance with the MDD or expired MDD certificate
-No significant technical changes to the medical device
-No unacceptable risk
-Quality management system (QMS) according to Article 10(9)
-The submitted application for the products to be brought under the MDR
-The agreed contract with the notified body for the certification of the products.

This means in detail:
The MDD certificates will not be extended and will expire no later than 26.05.2024! Instead of having a valid MDR certificate, the amended MDR now allows manufacturers to place products on the market based on the aforementioned requirements.

04. Do hospitals and doctors’ practices that are already operating non-MDR compliant medical devices have to replace them with MDR compliant products?

No. Medical devices that have been put into operation before the end of the transition period for the first time may continue to be used. However, the servicing of the devices must be MDR compliant.

05. What changes when calibrating scales?

Nothing. The calibration of medical scales is regulated by the respective national calibration regulations.

06. Where does the MDR apply?

The MDR applies to all member states of the European Union:

+ Belgium
+ Malta
+ Bulgaria
+ The Netherlands
+ Denmark
+ Austria
+ Germany
+ Poland
+ Estonia
+ Portugal
+ Finland
+ Romania
+ France
+ Sweden
+ Greece
+ Slovakia
+ Ireland
+ Slovenia
+ Italy
+ Spain
+ Croatia
+ Czech Republic
+ Latvia
+ Hungary
+ Lithuania
+ Cyprus
+ Luxembourg

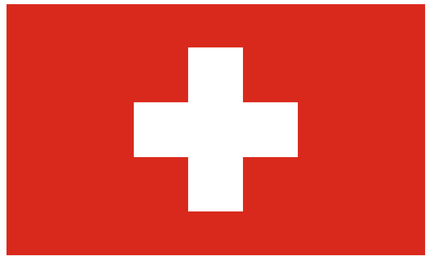
Does the MDR apply to the United Kingdom?

Since January 1st, 2021, the United Kingdom has no longer been part of the European Union (Brexit). Therefore, the MDR is not valid in the United Kingdom. Here, the UK Non-Automatic Weighing Instruments Regulations and the UK Medical Devices Regulations apply. New transition periods for medical devices are:

- June 30, 2028 for MDD-certified products
- June 30, 2030 for MDR-certified products

Without a conformity assessment based on the UK-MDR, medical devices can still be sold in the United Kingdom until these specified deadlines. After these deadlines, the products will require a UKCA marking equivalent to the European CE marking.

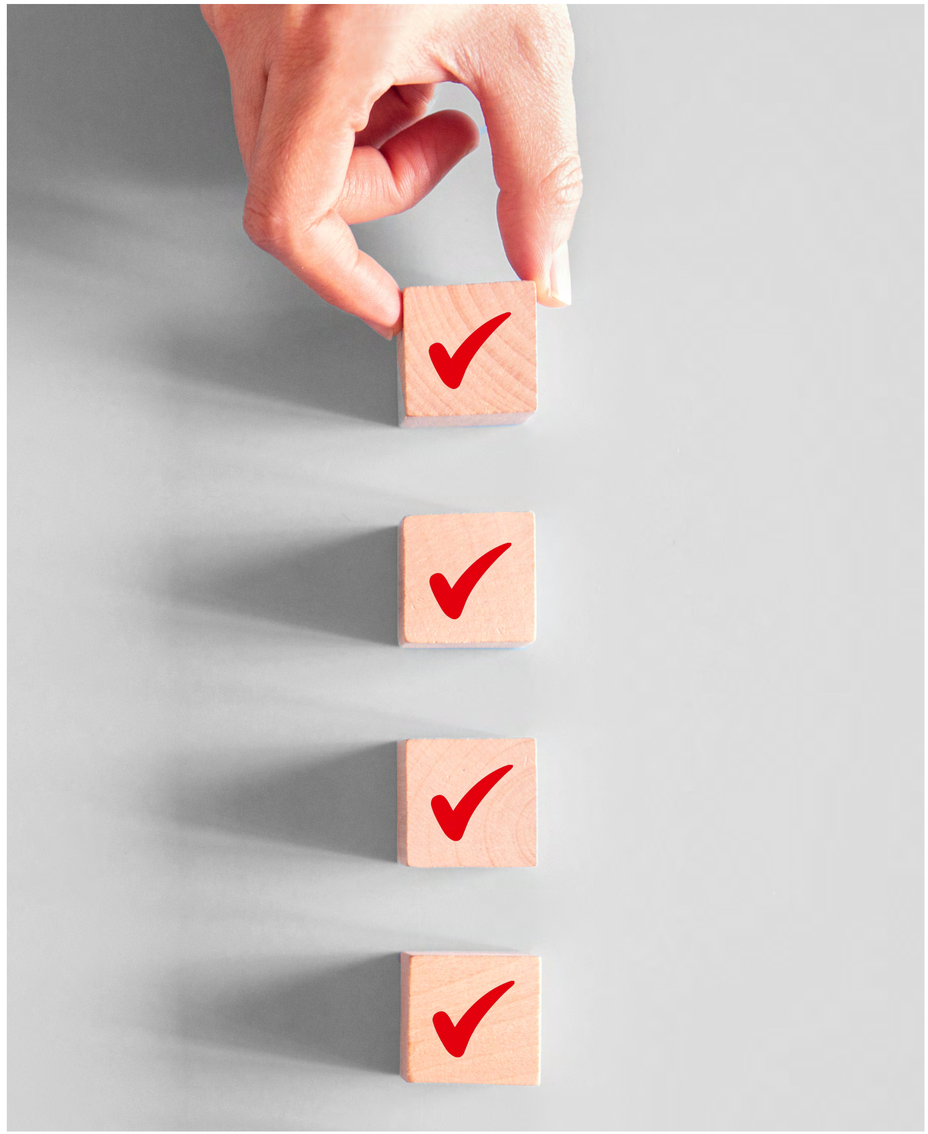
Is the MDR applicable in Switzerland?



Switzerland is not a member of the European Union. However, it has recognized MDD in the past. However, the corresponding trade agreement between the EU and Switzerland was not signed for the MDR. Thus, the MDR is not applicable in Switzerland. Here, the national medical product law applies, the Swiss Medical Devices Ordinance (MepV). seca fulfills all the requirements needed to sell its products according to the MepV in Switzerland.

07. What requirements must be met for a manufacturer to be MDR compliant?

1. The quality management system must meet the new requirements of the MDR.
2. The technical file must be MDR compliant.
3. A notified body (e.g. TÜV-SÜD, BSI, Intertek) carries out an MDR audit at the manufacturers and issues an EU certificate that certifies the conformity of the quality management system and the respective product group in accordance with the MDR.



08. From when is a product MDR compliant?

As soon as quality management and the technical files of the medical device meet the requirements of the MDR and the manufacturer of the medical device has a Declaration of Conformity as per the MDR issued.

09. What is a Declaration of Conformity?

With the Declaration of Conformity, a manufacturer confirms that the product concerned meets the requirements of the MDR (= Declaration of Conformity under the MDR) or the requirements of the MDD (= Declaration of Conformity under the MDD).

10. Does a service provider who maintains and repairs medical devices have to meet MDR requirements?

Yes, in Article 23, Section 1 of the MDR, requirements for parts and components are defined and this also applies to companies that use spare parts for maintenance and repairs:

companies that provide spare parts for damaged or worn medical devices in order to maintain or restore the function of the product

+ must ensure that they do not impair the safety and performance of the respective medical devices and
+ have evidence of this that must be made available to the authorities if requested.

11. Does seca fulfill the requirement of the MDR with its maintenance and repair service?

Yes. Yes, if damaged or worn components have to be replaced, seca replaces them with only original spare parts. For these, the manufacturer (seca) provided evidence (test reports) in the course of the development that prove that they do not impair the safety and performance of the repaired medical device.
This means that if a repair service uses spare parts that are not explicitly intended for the respective medical device, they are responsible for providing the required documentation themselves.

12. Do spare parts need to be MDR compliant?

Replacement parts are not medical devices, therefore they do not require a Declaration of Conformity under the MDR.

But: Evidence must be provided to demonstrate that they do not impair the safety or performance of the repaired product (see 10. and 11.) For example, this can be proof that a specific component, like a load cell, meets the EMV i.e. electromagnetic compatibility requirements.

13. What service intervals does the MDR stipulate?

The MDR does not stipulate any service intervals. These generally result from national laws for medical devices, measuring devices, electrical devices, etc.

14. Can MDD medical devices and and MDR medical devices be connected to the HIS together?

Yes.

15. What does the MD symbol mean?

Products that are subject to European directives or specifications and for which a conformity assessment procedure has been carried out, like electrical or medical devices, are marked with the CE symbol. The MD symbol (Medical Device) indicates to the layperson that this CE conformity assessment is a medical device, that complies with the MDR.

16. What is UDI?

+ UDI is the abbreviation for the Unique Device Identifier. It denotes a combination of numbers or a combination of numbers and letters that enables the clear identification of individual medical devices on the market.
+ All products for which a Declaration of Conformity has been issued according to MDR must bear a UDI number on the product itself as well as on the packaging. Different transition periods apply depending on the risk category of the medical devices.
+ Market monitoring is improved with the aid of the UDI. Products related to an adverse event can be traced back more easily and recalls can be carried out easier. Product counterfeiting is made more difficult.

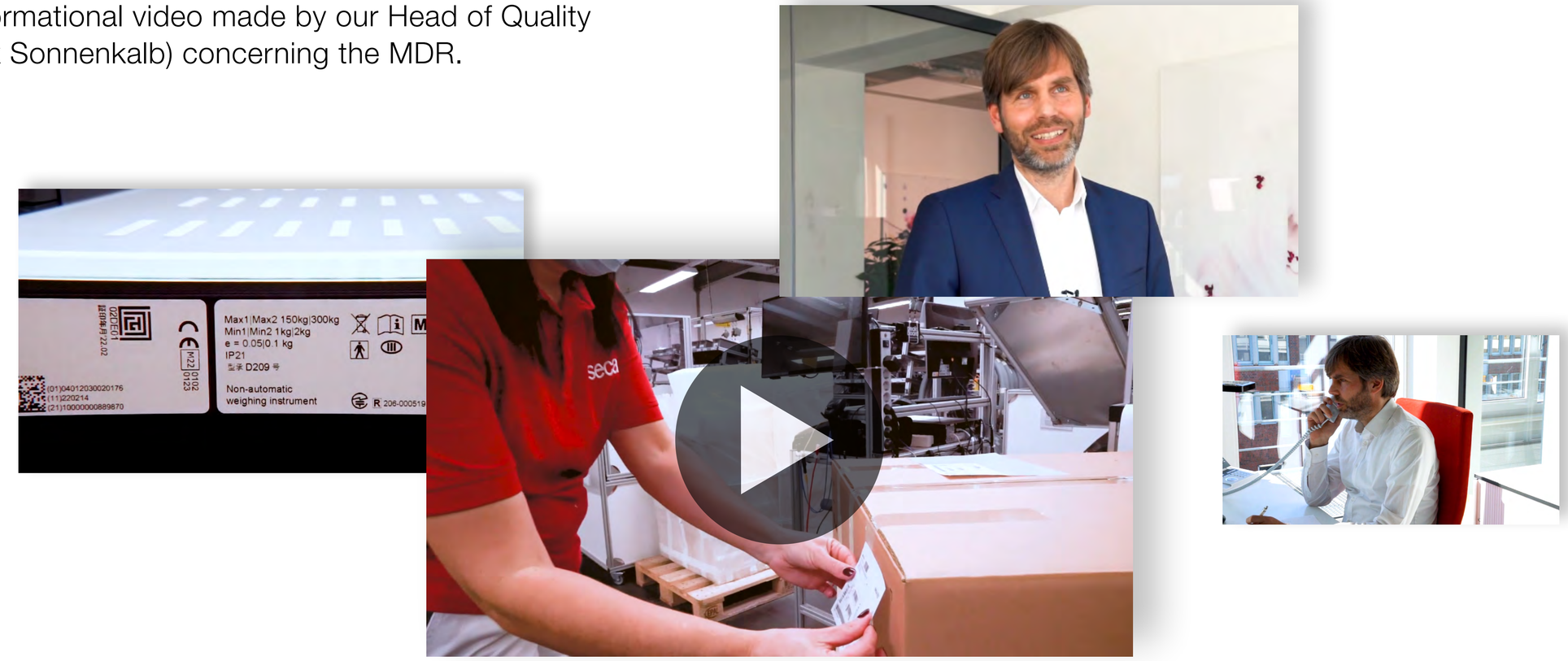
17. What is EUDAMED?

The European Database for Medical Devices (abbreviated to EUDAMED) is a database for the central administration of medical devices operated by the European Commission and EU member states. In this database,medical devices are registered by their UDI, or rather, the UDI database it part of EUDAMED.

The EUDAMED is supposed to make the life cycle of medical devices transparent. The authorities, as well as users and patients, have direct access to information about the manufacturer, products, study data, certificates and additional information. Market monitoring and patient safety is improved with EUDAMED. For example, governmental authorities can take or recall conspicuous medical devices from the market faster.

Any further questions?

Watch this informational video made by our Head of Quality Services (Mark Sonnenkalb) concerning the MDR.



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