The European Medical Device Regulation (MDR)

Medical Device Regulation (MDR)

Why MDR?

- With the new MDR, the EU is reacting to scandals involving defective medical devices by tightening the requirements for medical devices throughout Europe.
- The new MDR replaces previously applicable national directives such as the MDD, and therefore contributes to the harmonization of rules in the EU.

What are the aims?

- Increased protection of patient safety
- Greater transparency and traceability for all medical devices
- Better control and accessibility of the documentation

What are the most important changes?

- New classification rules for medical devices
- Stricter requirements for clinical evaluation, technical documentation, market surveillance and the vigilance system
- More comprehensive labeling of devices (e.g. UDI code) and reporting of device data to the European database EUDAMED

Timetable for implementing the MDR

05/25/2017
MDR enters into force

Deadline May 26, 2021
- Implementation of the MDR becomes mandatory.
- Devices can no longer be certified to MDD.

What this means for Dr. Schumacher:
- All Class I medical devices must be MDR-compliant.
- New Class IIa / IIb medical devices can only be placed on the market after successful MDR certification and notification.

05/26/2023
UDI placement on Class II devices

05/26/2025
UDI placement on Class I devices

2017 | 2018 | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | 2025

3-year transition period
(Certification of medical devices to MDD still possible)

Mandatory implementation of MDR postponed by 1 year due to the Covid-19 pandemic

"Grace period" for MDD-certified devices:
- Marketability stays the same, provided that no changes are made to the device
- Also applies to AIMDs
- Class I medical devices are excluded

05/26/2024
All medical devices must be MDR-compliant

Dr. Schumacher GmbH, Am Roggenfeld 3 / 34323 Malsfeld / Germany, T +49 5664 9496-0 / F +49 5664 8444, internationalsales@schumacher-online.com, **www.schumacher-online.com**

Implementing the MDR at Dr. Schumacher

With the MDR coming into force, Dr. Schumacher has initiated all the necessary measures to ensure that all medical devices are transferred safely and on time to the MDR.

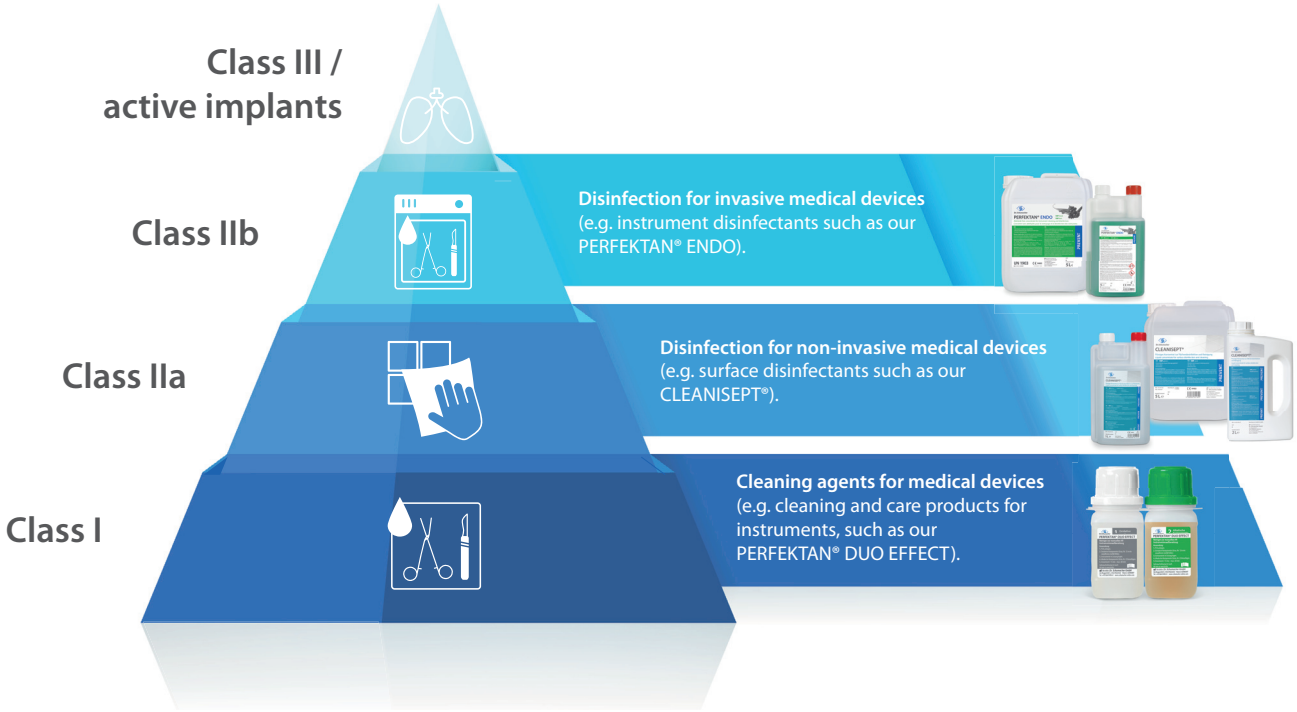

Illustration based on BVMed

Correctly compliant with Dr Schumacher

- As from May 26, 2021, all Class I medical devices will be placed on the market in accordance with MDR requirements.
- Within the applicable deadlines, Class IIa and IIb medical devices remain marketable in accordance with their MDD certification and are gradually being converted to the requirements of the MDR.

Complete, available and responsible

- The Dr. Schumacher portfolio is available in its entirety, without any restrictions
- Reliable availability of the products is assured.
- Dr. Schumacher takes responsibility for protecting users and patients.

Dr. Schumacher GmbH, Am Roggenfeld 3 / 34323 Malsfeld / Germany, T +49 5664 9496-0 / F +49 5664 8444, internationalsales@schumacher-online.com, **www.schumacher-online.com**