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Quick Facts

Medical Device Regulation (MDR)

7 facts about the MDR – what you need to know now about Medical Device Regulation and your power supply

Through the entry into force of the MDR, the European Union has set up a framework of new, significantly stricter regulations for medical devices. The rules present a great challenge for companies. Moreover, a great deal of uncertainty concerning the effects of MDR remains. Despite the obstacles, medical device manufacturers should not waste time and should now focus on implementing the stringent regulation so as to keep their products on the market.

Here is a summary of the most important facts:

- The Medical Device Regulation (MDR) is officially known as Regulation (EU) 2017/745. It replaces the previous medical device directives, 90/385/EEC and 93/42/EEC, with a single, uniform standard.
- The MDR covers a wide range of new documentation and labeling requirements, including regulations for a unique identification number (UDI) or conistent traceability.
- Due to the coronavirus pandemic, the MDR transition period has been extended by one year to May 26, 2021.
- MDR conformity must be confirmed by the manufacturer within the scope of their CE declaration.
- An independently produced power pack is not a medical device and is also not considered an accessory within meaning of the MDR. On account of this fact, the power supply manufacturer may not include MDR conformity in their CE declaration.

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- One exceptional case in which a power pack may be considered an accessory for a product is if a medical device manufacturer explicitly requests the use of a specific power pack (in the user manual, for example). Such cases necessitate a separate CE declaration for the power pack.
- In this case, the producer of the power pack is the supplier rather than the manufacturer within the scope of the MDR. As a result, the obligation to issue a CE declaration of conformity for the power pack is transferred to the medical device manufacturer.

Questions?
Discuss your needs and concerns directly with our experts. Your qualified contact for medical technology at FRIWO:

Gerrit Menzel
Area Sales Manager
P +49 (0) 2532 / 81 311
C +49 (0) 152 / 02 02 13 08
gerrit.menzel@friwo.com

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