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The Medical Device Regulation (MDR) presents a challenge for medical technology

What you now need to know about your power supply

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Whitepaper

The Medical Device Regulation (MDR) presents a challenge for medical technology

What you now need to know about your power supply

We now know that the official application of the Medical Device Regulation has been postponed for one year due to the impact of the coronavirus pandemic. Manufacturers have therefore gained additional valuable time to prepare for the implementation of this ambitious directive. But what do companies need to know specifically about the standard power supply of their medical device to ensure a smooth transition to the new regulations on ***May 26, 2021****, and keep their products on the market? And what should medical device manufacturers generally look for when choosing their power supply? This white paper provides an explanation.*

New medical technology requirements

With the MDR taking effect, manufacturers of medical devices are faced with a wealth of new documentation and labeling obligations. In this context, medical devices must also be equipped with a unique device identification number (or UDI) and offer full product traceability. However, because the MDR requirements are complex and differ in practice depending on the function and area of application of the components, this rule does not, by any means, apply to every single medical product and its components. The requirements also differ significantly depending on the role and position of the respective company in the supply chain.

CE declaration: different roles of companies and their obligations

In order to understand which regulations apply to the use of power supply units for your medical device, you first need to be aware of the different functions of the economic operators.

The MDR – what exactly is it?

MDR stands for Medical Device Regulation.

To give it its full title, it is Regulation 2017/745 of the European Parliament and of the Council on medical devices. The new regulations came into force on May 25, 2017, and replace the previous medical device directives 90/385/EEC and 93/42/EEC with a single, uniform standard.

The MDR is immediately applicable in all member states of the European Union and therefore does not need to be put into national law. As a result, the MDR also replaces the German Medical Devices Act [Medizinproduktegesetz (MPG)] and its national regulations (MPV, MPSV, DIMDIV, etc.).

Originally, the MDR should have been made binding for all market participants in May 2020, following a three-year transition phase. As a result of the coronavirus pandemic, the transition deadline has been extended by one year. The new deadline for compliance with MDR rules is now May 26, 2021.

The new MDR defines five roles in this regard:

- Manufacturer
- Authorized representative (EC rep)
- Importer
- Distributor
- Supplier/sub-contractor

An essential requirement for the marketing of products in the European Economic Area is the CE declaration of conformity. In general, the manufacturer of the medical device is responsible for this declaration. Manufacturers should therefore ensure that their product complies with the MDR conformity requirements.

Note: The manufacturer is not automatically the manufacturer of the medical device as defined by the MDR; the MDR might define the manufacturer as a supplier or sub-contractor!

For high-risk medical devices, a CE declaration of conformity can only be made with the help of what is known as a notified body. A notified body is a private or state investigation site that operates under a state mandate and supports and monitors the conformity assessment of manufacturers.

Are we heading toward an authorization bottleneck?

The medical industry could still face a real capacity bottleneck when it comes to authorization. A total of 56 investigation sites have been accredited to monitor the soon-to-be-replaced Medical Device Directive. Yet, more than three years after it was announced, only 14 investigation sites have been accredited as notified bodies for monitoring the MDR.1 In the meantime, manufacturers of medical devices should therefore plan for longer authorization timelines for their new products.

MDR scope of application: Do the rules also apply to power supply units?

The MDR by no means applies to all medical devices or their components. Determining whether the new regulation also applies to a device's power supply requires detailed research and leads to different results depending on the type of power supply.

For the purposes of the MDR, a medical device is one that has an intended medical purpose or is listed in Annex XVI of the MDR. Neither of these definitions applies in the case of power supply units.

In theory, manufacturers themselves can define an intended medical purpose for their products - but only if the product has a medical or therapeutic effect. This is not the case for power supply units.

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1 Accessed from NANDO on May 27, 2020: http://ec.europa.eu/growth/tools-databases/nando

An independently produced, standard power supply unit is therefore not classified as a medical device by the MDR

It still remains to be decided whether a power supply is an accessory of a medical device as defined by the MDR, which would then be associated with corresponding obligations. In order to be classified as an accessory for a medical device, the manufacturer must clearly assign the component to a specific medical device. This is not possible for the manufacturer of a standard power supply unit, because power supply units can be used by a wide range of equipment.

An independently produced, standard power supply unit is therefore not classified as a medical device accessory as defined by the MDR, either

In summary, an independently produced power supply unit is not a medical device and cannot be classified as an accessory for a medical device.

The MDR therefore cannot be applied to an independently produced, standard power supply unit. For this reason, the manufacturer of the power supply unit may not include conformity with the MDR in its CE declaration.

Please note: there is an exception! When does my power supply unit need its own CE declaration?

A power supply unit can be classified as an accessory for a product as defined by the MDR if a manufacturer of a medical device explicitly requires the use of a certain power supply unit and excludes the use of other power supply units in the device user manual, for example. In this case, a separate CE declaration is required for the power supply unit.

*Unless a medical device manufacturer explicitly requires its use, the MDR does not apply to independently produced, standard power supply units such as FOX**NEO**.*

If the manufacturer explicitly requires the use of a specific power supply for the respective medical device, the MDR can be applied for the power supply unit!

Please note: In this case, the manufacturer of the power supply unit 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 supply unit is transferred to the medical device manufacturer. The manufacturer of the power supply unit can only provide advice and assistance.

For which directives are manufacturers of power supply units authorized to issue a CE declaration themselves?

- Low Voltage Directive (2014/35/EU)
- Directive on electromagnetic compatibility (2014/30/EU)
- Directive on ecodesign requirements (2009/125/EC)
- RoHS Directive (2011/65/EU)
- REACH Directive (2006/1907/EC)

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Quick Check

Medical Power Supplies

Six requirements that your medical power supply should meet

The power supply unit represents the heart of your medical device. It supplies the equipment with the energy it needs. As such, the same bottom line applies here as in the human body: If the heart fails, everything fails. Shortcomings here can have disastrous consequences in medical technology – just imagine what might happen if ventilation equipment were to fail, for example.

In order to avoid a potential worst-case scenario, medical device manufacturers must pay attention to a few important points when choosing their power supply.

- ✓ For use in medical environments, power supplies must comply with the EN60601-1 safety standard relevant for medical devices.
- ✓ The stringent EN60601-1-2:2015 requirements concerning the electromagnetic compatibility for medical devices and their environment must also be met.
- ✓ The requirements set by these standards are significantly more rigorous than for power supply units made for use in IT or multimedia applications
- ✓ Make sure to discuss the decisive technical features of the power supply in detail with your power supply manufacturer.

  Examples include:

  - Means of operator protection (MOOP) and means of patient protection (MOPP)
  - Minimal leakage currents
  - Increased voltage resistance

- ✓ The design and production of any power supply unit should be inspected by an accredited investigation site
- ✓ Power supply manufacturers should have a comprehensive risk and quality management system in place. Basic certification in accordance with the extensive ISO 9001 standard and certification in accordance with EN ISO 13485 (quality management system for medical technology) are highly beneficial

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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About the company

Since the discovery of the first plug-in power supply unit in the world, our demanding customers have been able to fully rely on an experienced partner for their power supply needs. As an international manufacturer of technically leading chargers, battery packs, power supply units, and LED drivers, FRIWO provides a whole host of applications with tailored solutions.

In a dynamic market environment, the company has continued to develop strategically and is today a systems supplier. Along with renowned power supply solutions, FRIWO also offers digitally controllable drive solutions from a single source. The product portfolio includes all components required for modern electric drives, from the display and motor control unit to the battery, charger, and control software.

With modern development centers, manufacturing facilities, and sales locations in Europe, Asia, and the US, FRIWO is present in all of the world's key markets. Our customer base includes renowned global companies in future-oriented industries such as electromobility, medical technology, industrial automation, and battery-powered tools.