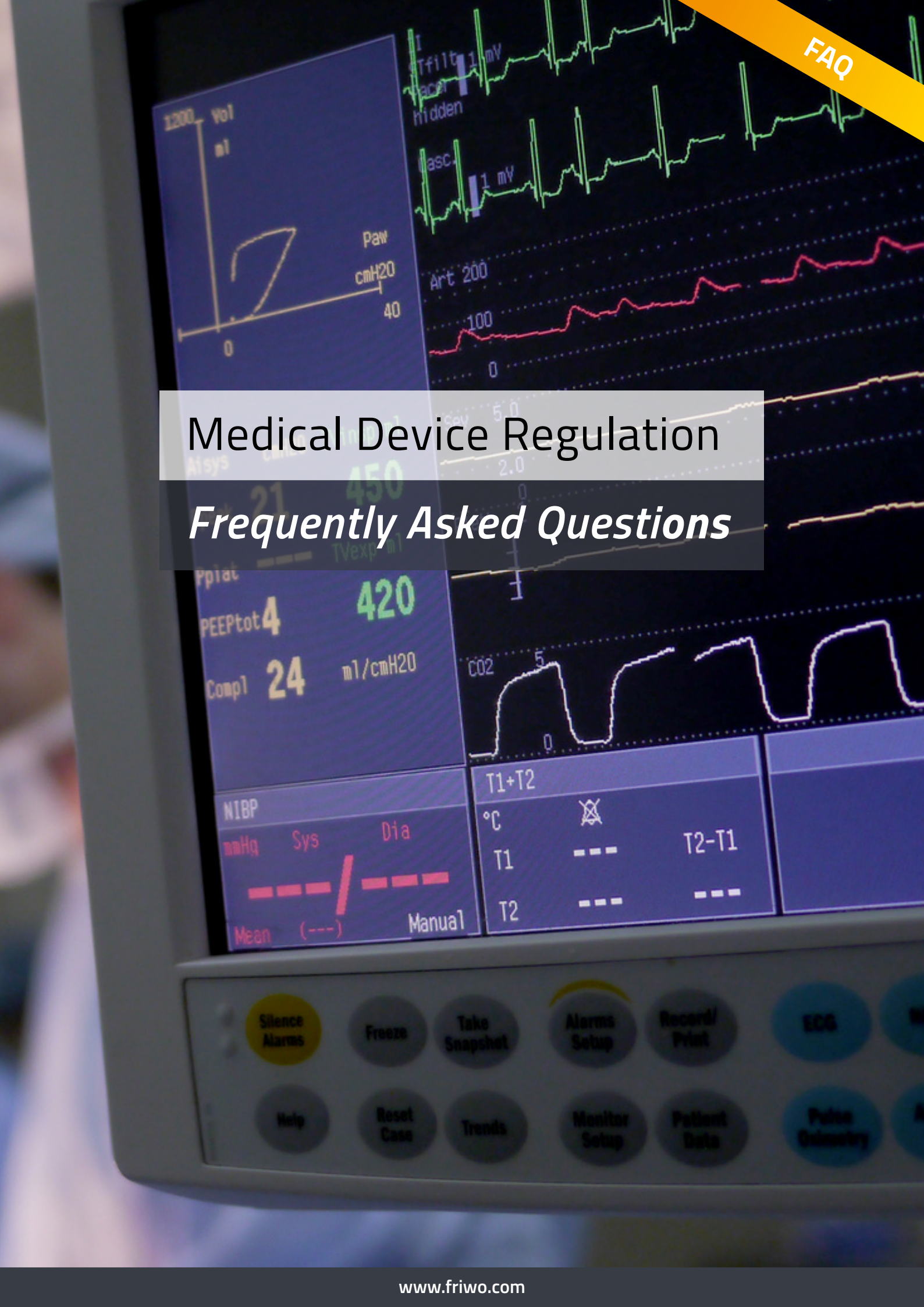
FAQ
Medical Device Regulation
Frequently Asked Questions
www.friwo.com

# Frequently asked questions on the challenges presented by the Medical Device Regulation

The final implementation date for the EU Medical Device Regulation (MDR) is getting closer. For manufacturers of medical devices, the clock is ticking – and in many respects there is still uncertainty about what effects the MDR will have from **26 May 2021**. We shed some light on the topic from a power supply perspective and have provided some answers to the most frequently asked questions.

### *Q: What changes will be made with regard to the labeling (identification plate/IFU) of FRIWO power supply units?*

**A:** If medical device manufacturers' power supply units have not been defined as components in accordance with the MDR, there won´t be any changes necessary to the labeling of FRIWO power supply units.

### *Q: Will labeling be coordinated with manufacturers?*

**A:** If medical device manufacturers' power supply units have been defined as components in accordance with the MDR, the labeling must be coordinated.

### *Q: Which company name has to be on the CE marking on the power supply unit?*

**A:** If medical device manufacturers' power supply units have been defined as components in accordance with the MDR, the CE declaration is made in the name of the medical device manufacturer, with FRIWO acting as a supplier / subcontractor and not as a manufacturer.

As a manufacturer of power supply units, FRIWO can only issue a CE declaration in accordance with the following directives·

- Low Voltage Directive (2014/35/EU)
- Electromagnetic Compatibility Directive (2014/30/EU)
- Ecodesign Directive (2009/125/EC)
- RoHS Directive (2011/65/EU)
- REACH Directive (2006/190/EC)

### *Q: Is the UDI defined by standard?*

**A:** The unique device identification (UDI) is linked to the certification database in the EU. The UDI can be issued or allocated by a number of bodies, at the moment these are the GS1, HIBCC and ICCBBA.

The UDI consists of two components: the UDI-DI and the UDI-PI.

The UDI-DI (UDI device identifier) is for the purpose of product and manufacturer identification and must be applied to the product itself and its packaging.

It contains information such as the trade name, recycling instructions, sterility, etc. There are approximately 20 different data points. Depending on the body issuing the UDI, it also contains a GTIN (global trade item number) (GS1), a UPN (universal product number) (HIBCC) or an ISBT 128-PPIC (processor product identification code) (ICCBBA).

The UDI-PI (UDI production identifier) marks the product batch and includes lot or batch numbers, serial numbers, expiry date and/or manufacturing date, among other information.

**A list of documents provided by the European Commission on the topic of UDI as endorsed by the MDCG (medical device coordination group) can be found here:**
ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

***Q: In EN 60101-1:2006 + A1:2013, the use of a class II medical-electrical device to protect against electric shock is not considered permissible.***

**A:** To reduce the risk of an electric shock, a medical device must have at least two protective measures – 2xMOOP or 2xMOPP; these measures can also be provided by means of a suitable power supply unit.

***Q: If an external power supply unit is approved according to EN 60601-1, is it a sufficient means of protecting against electric shock or are further measures necessary?***

**A:** There is no single answer to the question of whether an external power supply unit with EN-60601-1 approval provides sufficient protection against electric shock, as this depends on the nature and function of the medical device.

***Q: Is the MOPP/MOOP test voltage to be applied in AC or DC?***

**A:** The test voltage for power supply units is normally applied in AC.

***Q: If there is a direct connection, does the power supply unit then not fall under the scope of the MDR in terms of unique identification?***

**A:** If medical device manufacturers' power supply units have been defined as accessories in accordance with the MDR, the MDR applies to both the medical device itself and the accessories.

### *Q: If an additional equipotential bond is required, is that even possible in protection class II (if the device is not portable)? Or is the equipotential bond only intended for use in medical rooms?*

**A:** Medical devices in use at home that do not have a fixed connection to the power source may only be powered with class II power supply units or internally in accordance with EN-60601-1-11. The use of functional earthing is also not permitted.

This is because many houses do not possess properly functioning earthing. In the case of protection class I devices, a fault causes the power to flow to the earth through the protective conductor and trips the residual current device (RCD) or a fuse. This can lead to a fatal electric shock in buildings without proper earthing installed. Protection class II devices have double insulation and are safe in the event of a fault.

Functional earthing serves to suppress electromagnetic interference, but if no earthing is installed this can lead to malfunctions due to the inadmissible interference level.

This is not the case with protection class II devices without functional earthing.

### *Q: What distinguishes a protection class I power supply unit with type B floating ground?*

**A:** Medical devices have so-called “applied parts” if there has to be an electrical connection between the medical device and the patient. This is the case, for instance, for the electrodes on an ECG measuring device but also on the surface of an X-ray examination table. This link between the patient and the device is called the patient connection.

There are three types of applied parts: B, BF and CF. Type B parts have the least stringent requirements. In this case B stands for “body” in reference to the body’s connection to the earth. Class I power supply units have a protective earth connection and are therefore earthed.

The power supply unit protection class is not linked to the type of applied part, but is easier to design depending on the power supply unit type.

**Further information on MDR** can be found in our MDR facts, MDR whitepaper and the power supply checklist on our website:
**friwo.com/en/sectors/medical/**