EU-MDR

FAQ MDR

The MDR (Medical Device Regulation) is now entering its final phase and the questions will most likely increase in frequency. This guide is to help you to answer any potential questions.

Our medical products are: Lucro, My Generation and Post-OP. The documentation for further potential medical devices (e.g. Pavlik trousers) is currently under review and will be added to the downloads page as soon it is fully in order.

*"Where can I get your **conformity declaration**? Can you send it to me?"*
- download page

Our downloads page is constantly being extended with new conformity declarations, so that at the time the MDR becomes fully binding (26 May 2021) all the necessary data will be made available to our customers.

*"I need **an operation manual** (e.g. Lucro classic) for my files. Where can I get these?"*
- download page
- Included with medical device

The operations manuals are also available to customers for download on our internet site (as a PDF file in 33 different languages). In addition, we should make the customer aware that we include operation manuals with every medical device ordered. So the customer will also receive operation manuals with their order.

*"Who is the **"qualified person"** at your company? Do you have such a person?"*
- It is a requirement ("qualified person" at Schein: Mr Felek)
- Is named in conformity declarations

A "qualified person" is required by the regulations of the MDR and will of course be named by us. This is guaranteed by the issuance of the conformity declaration; the person's signature even gives their name. However, our "qualified person" is not of relevance to our customers as giving this information is not required of the customer (e.g. medical supply store).

*"Why do your **insoles not have a CE label**? I thought they were medical devices?*
- We sell blank insoles (raw material to create an insoles)
- The technical specialist turns them into a medical product

All Novaped blank insoles from ´Schein Orthopädie Service KG´ are to be considered as raw materials for the creation of specialised products and so are not supplied with a CE label. However, all products are checked as per Appendix I of the MDR. The health care technician further processes the blank, according to medical prescription, for each customer individually, making it into a medical device (specialised device).

*"Why have I not received an **operation manual with the insoles**? I need them for my files."*
- Our blank insoles are not a medical device no operation manual necessary
- Reference to processing instructions in the downloads page

Our blank insoles are intended for further processing by a technician and only then become a specialised product. For this reason, the blanks themselves are not a medical device and do not need the operation manuals for end customers that a finished product requires. For the important stages of further processing, we have provided processing instructions for technicians in our downloads page.

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schein orthopädie service
Germany since 1879
We help

*"Why can I not find the conformity declarations of your **diagnostic devices** on the downloads page? Why do the diagnostic **devices no longer have a CE label**?"*

- They are not diagnostic devices aids in condition measurement
- They are not medical devices (devices cannot provide diagnoses)

On the basis of the new legal requirements of the MDR, we have re-examined and evaluated the status of our measurement and test systems. We have decided that our measurement and test systems are not diagnostic devices.

Our measurement devices are promoted and sold under the label "aids for measuring medical condition". It is to be understood that the purpose of the devices is not the determination of diagnoses, but only the documentation or communication of the patient's condition.
These devices are only sold to those in auxiliary medical occupations. Our customer base, and our company itself, is not authorised to issue diagnoses. As these are not medical products, they do not need to conform to the MDR (no conformity declaration, no CE label and no UDI).

"Competitors have a CE label on their diagnostic devices but you don't! Why?"

- CE label is not a "quality seal"
- Only the MD label (medical device) shows that the conditions of the MDR have been applied
- We sell aids for recording patient condition, not diagnostic devices (medical products)

The CE label only shows that the product is in conformity with a legal directive. The CE label does not define the exact guideline, so there is a possibility that the product has been tested to a completely different guideline (examples of other guidelines: hot-plate to the Machinery Directive, a mobile phone to the Electromagnetic Compatibility Directive, toys to the Toy Safety Directive and the MDR for medical products). Only if the label "MD" (medical device) is applied can it be clearly stated that the CE-labelled product conforms to the MDR. As we do not distribute diagnostic devices, but rather measurement devices to aid in determining patient condition, our products are not medical products. For this reason, we have not applied a CE label. However, our measurement devices fulfil all quality criteria (as always) and can be used on/applied to the patient without reservations.

*"Up to what point am I allowed to buy **noncompliant products/ products with an "old" label?**"*

- From 26.05.2021, all our medical products will conform to the MDR
- Products previously bought from us can still be sold up to 26.05.2025

Our products will conform to the MDR fulfilling all the requirements by the latest from 26.05.2021. If a customer (e.g. medical supply store) bought a medical device before 26.05.2021 from us, they can sell this product up to 26.05.2025 as these are considered to have already been placed on the market. It is not relevant here whether the label complies with the old or the new standard.

*"How can I know **the device is compliant to MDR**?"*

- There will be the following data on the label: MD label, UDI, expiry date
- From 26.05.2021, all our medical device will conform to the MDR

If the label shows all the new characteristics relevant to the MDR (MD label, UDI and expiry date) then the product bought from us is conformant with the MDR. Of course, this will be fulfilled by the latest from 26.05.2021. Medical devices purchased before 26.05.2021 may still have the "old" label, these products can be sold until 26.05.2025.

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*"What is the **UDI** and where can I find it out?"*

- UDI = Unique Device Identification
- It is on the packaging (label): numerical and data matrix

The Unique Device Identification (UDI) is a product identification number ensuring the product can be traced back to the manufacturer. It is applied individually to each product and gives information on the manufacturer, batch number/expiry number and product number. The UDI is shown in a numerical (human-readable) and encoded (machine-readable) form. Both variations are on the item packaging label and can be read or digitally scanned with a 2D scanner.

*"**QM certificates**: why not DIN EN ISO 13485 instead of ISO 9001: 2015?"*

- MDR does not explicitly specify a standard
- ISO 9001 is a standard on the establishment of a quality management system

In the MDR, a quality management system is required (MDR 2017/745, art. 10, point 9) but no explicit standard is named. In addition, external certification for Class I medical device is not required. We have decided to set up a QM system as per ISO 9001 (since 1997) and also have it externally certified. The external certification is currently valid to May 2022 and will then be renewed. Through the issuance of the conformity declaration, we guarantee that all processes all the way to follow-up evaluations have been reliably carried out.

*„What are the meanings of the symbols on the new **labels for medical devices**, using LucRo as an example?"*