The new MDR – Medical Device Regulation.

Medical Device Regulation 2017/745

The new EU Medical Device Regulation: What is changing?

The Medical Device Regulation (MDR) was published in the Official Journal already on 5 May 2017 and became applicable on 25 May 2017, together with the regulation on in vitro diagnostic medical devices. The national transition period of the MDR will expire on 26 May 2020.

Medical device verification using UDI

The MDR increases the cost and effort for manufacturers of medical devices in particular. It comes with a unique device identification (UDI) system similar to securPharm and the new pan-European database Eudamed, where all medical devices sold in the EU are supposed to be registered including the manufacturer and/or importer as well as the authorised representative.

What is changing for our customers?

The topic is relevant now and people wonder: How will the introduction of the MDR actually affect us? What do we have to do and what are our obligations? We are asked these questions every day. To prevent the mushrooming of wild speculations, we have put together the most important points for our customers.
The scope of the new regulation has significantly increased compared to the old directive (93/43/EEC). Particularly the role of the manufacturer as the main responsible authority and the related tasks and obligations feature more prominently.
Whether the action taken by the EU will remedy errors and failures or whether it will cause new, even more serious problems – that remains to be seen in the next years. Of course, such an assessment will be also dependent on individual judgement.
Consulting companies or notified bodies offer training and seminars for manufacturers; however, other business players will have to fend for themselves when it comes to acquiring the necessary know-how.
Due to our obligations as a manufacturer, we have looked into the MDR in great detail. Therefore, we would like to share our knowledge and experience with our customers. AMPri's customer base largely consists of resellers (distributors), which we would like to support. The following summary will give you a short overview of a distributor's obligations according to the Medical Device Regulation 2017/745.

The obligations of a distributor

- Exercising general due diligence with regard to all applicable requirements.

Obligation 1: (Article 14 paragraph 2 a) of the MDR):

- Verifying whether the device has been CE-marked and whether a declaration of conformity has been drawn up.

Fulfilment:

- Verifying the marking relevant to your risk category, supplier assessment, and quantities when inspecting incoming goods (sampling method).
- Requiring a declaration of conformity from the manufacturer of the device.
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Obligation 2: (Article 14 paragraph 2 b) of the MDR):

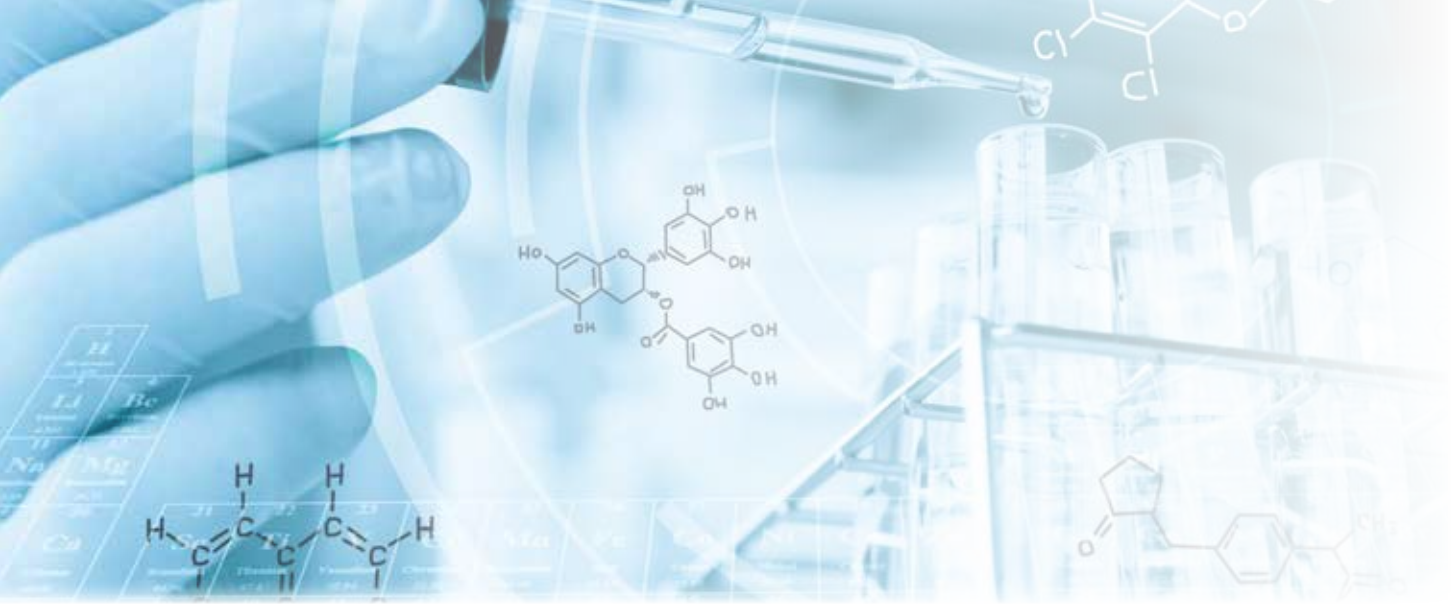
- Verifying whether the device is accompanied by the information required in accordance with Section 23 of Annex I.

Fulfilment:

- Language is a major criterion to be verified. Is the information available in the language of the target country? Some information required is optional, depending on the devices – which is why not all information can be listed. Again, this can be verified when inspecting incoming goods.

Obligation 3: (Article 14 paragraph 2 c) of the MDR):

- Imported devices (with manufacturers outside the EU) need to be verified as to whether the importer has complied with the requirements set out in Article 13 (3).



Fulfilment:

- Is the marking sufficient to establish the location of the importer? Name, address, trade mark. Labels must not obscure any information provided by the manufacturer.
- Ensuring that the EU representative has been named.
- **IMPORTANT!** These checks are always necessary. Inclusion in a sampling procedure is not required.

If the manufacturer is based in the EU, the importer's obligations and, thus, the above verification by the distributor are irrelevant.

Obligation 4:

- Verifying that a UDI (Unique Device Identifier) has been assigned by the manufacturer.

Fulfilment:

Depending on the classification of the medical device, manufacturers have to label their devices using a Unique Device Identifier. This labelling on the packaging is required for the following classes:

- Class I = 26 May 2025
- Class IIa & IIb = 26 May 2023
- Class III = 26 May 2021

We have prepared this information for you to get an idea about what the MDR requires. Do not hesitate to contact us if you have any questions. If required, we also offer intensive training courses at the AMPri Academy where you can delve deeper into the ramifications of the MDR or acquire better knowledge of our products etc. Please, get in touch if you have any training requirements.

Best regards from the AMPri team

AMPri Kompetenzzentrum Labor und Academy

AMPri Academy

AMPri Labor

The **Competence Centre** consists of the **AMPri Academy** and the **AMPri Laboratory** (scientific director: Johanna Hühn, glove expert). Here, specialist knowledge is presented in a well-structured way by competent trainers. That is what participants can expect from a seminar at AMPri. Seminars and training courses are either geared towards specially requested products or developed on a more comprehensive basis. We also offer company training courses that deal specifically with our customer's product range. The contents of a seminar are individually tailored to customer requirements – that is, to your requirements. In addition to the training courses, we carry out material tests in our new laboratory in the Competence Centre.

If you, as our customer, wish to select the best gloves for your or your customers' applications, it makes sense to use **DATAChem**. DATAChem is the only database giving the breakthrough times of chemical gloves that also makes possible the evaluation of complex mixtures. The diverse range of services offered by the Competence Centre is available at all times to all who are interested. If you have questions regarding the Competence Centre, please, do not hesitate to get in touch with the AMPri Team at **academy@ampri.de** (Academy), **info@ampri.de** (laboratory) or at +49 4171 8480-0.

AMPri

AMPri Handelsgesellschaft mbH · Benzstraße 16 · 21423 Winsen/Luhe · Germany
Tel.: +49 (0) 4171 8480-0 · E-Mail: info@ampri.de

www.ampri.de