

ANNEX TO THE GENERAL TERMS AND CONDITIONS (AGB) CONCERNING COMPLIANCE WITH THE REQUIREMENTS OF THE EUROPEAN UNION MEDICAL DEVICE REGULATION EU (2017/745)

1 Preliminary remark

From May 26, 2017, the Medical Device Regulation (MDR) (Regulation EU 2017/745) applies across Europe. The new Medical Device Regulation (MDR) replaces the directive 93/42/EEC for medical devices. As a regulation, the MDR is directly applicable. It is binding for manufacturers and distributors at all stages of trade as well as the other operators; these parties are obliged to comply with the duties stipulated therein. The transitional period for the implementation of the MDR ends on May 25, 2021, which means that the regulation becomes directly applicable from that date.

The MDR imposes extensive obligations on distributors (Art. 14 MDR) and manufacturers (Art. 10 MDR) that each apply independently but must be fulfilled in combination with one another.

2 Purpose of the annex

This annex from Bauerfeind AG is intended as a tool and aid, in particular for its quality partners/customers, to clarify the obligations for distributors defined in the regulation and to ensure joint fulfilment of our mutual obligations as manufacturer and retailer.

As a result, the annex should make a significant contribution to safety in the supply of medical devices (from Bauerfeind).

The following conditions are intended for clarification and coordination of mutual responsibilities as well as straightforward, effective and reliable implementation of the legal obligations in line with patient and consumer protection.

Implementation is always determined by the current wording of the MDR and its implementing rules, taking any validity periods into account.

3 Implementation of manufacturer obligations

Fundamentally, Bauerfeind AG is a manufacturer of ready-to-sell medical devices. Accordingly, Bauerfeind is subject to the general obligations under Art. 10 of the MDR. In particular, these include that the medical devices produced by Bauerfeind must be manufactured and brought on the market according to the requirements of this regulation and that a risk management system must be established, documented, applied and maintained. Insofar as Bauerfeind AG manufactures and/or distributes medical devices that are not ready for sale, separate conditions apply in this regard.

4 Implementation of distributor obligations

'Distributor' within the meaning of the MDR (Art. 2 (34) of the MDR) "means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service."

In this context, a distributor is also considered to be one of the economic actors listed in Article 2 (35): "Economic operator means a manufacturer, an authorized representative, an importer, a distributor...".

Distributors have the following general obligations in accordance with **Art. 14 MDR**:

- Formal obligations to inspect and inform in the event of non-conformity before making products available on the market (section 2);
- The distributor must ensure the storage and transport of products according to the conditions set by the manufacturer (section 3) as well as
- obligations concerning information, cooperation and documentation as part of market monitoring after making the products available on the market (section 4-6).

In addition, specific obligations apply in the respective context, particularly if these are generally directed at economic actors (which include distributors along with manufacturers, authorized representatives and importers). These include the following:

- Ensuring an appropriate level of traceability for products within the supply chain (Art. 25, Art. 27 (8) MDR);
- Implementing corrective actions within the framework of market monitoring carried out by the authorities (Art. 95 (1) and 3 MDR);
- Where relevant, the registration of distributors in accordance with the respective national provisions (Art. 30 (2) MDR);
- The obligation of on-going product observation after bringing medical devices on the market (see Art. 25 (1) MDR concerning traceability in conjunction with the post-market surveillance obligation in accordance with Art. 2 (60) MDR).

Traceability

In order to ensure traceability, the distributor and its customers must in principle establish the following:

- An agreement concerning their collaboration;
- The distributor's obligation to keep information available for the authorities, including the establishment of an appropriate method and documentation, e.g. in accordance with ISO 13485 as well as
- a regulation for cases involving the cessation of business or insolvency on the part of the distributor.

In line with the provisions regarding traceability, the distributor assures Bauerfeind AG that it is possible to individually contact all recipients of medical devices from Bauerfeind AG in order to hand over specific safety-relevant information and instructions to them or to consult these recipients appropriately in this regard. Acceptance and documentation of experiences, findings and other information about the products

In addition, distributors are obliged:

- To document, retain and continuously update the experiences, findings and other information about the products;
- To implement suitable procedures for acceptance and retention, and
- To establish a regulation for cases involving the cessation of business or insolvency on the part of the distributor.

The distributors will provide Bauerfeind AG with their findings and experiences and other information concerning the products and practical experiences either at the request of Bauerfeind AG, or as warranted without being requested to do so. Supplementary provisions to ensure the MDR regulations are derived from the General Terms and Conditions of Bauerfeind AG as well as the BQP contract.

Support with customer surveys

Distributors are also obliged:

- To support the manufacturer by forwarding experiences, findings and other information about the products/goods, and
- To forward all experiences, findings and other information to the manufacturer, particularly where there is suspicion of serious incidents or serious danger to public health.

Advertising

The distributors have a general obligation only to use advertising materials that have been approved by the manufacturer.

5 Distinction of product ranges

Generally, Bauerfeind medical devices feature a CE marking. In this way, Bauerfeind AG ensures that the medical device in question complies with the MDR. Custom-made devices, in accordance with Art. 2 (3) of the MDR Regulation, are products specifically made in accordance with a written prescription of an authorized person, e.g. a physician, which stipulates, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.

However, mass-produced devices which need to be adapted to meet the specific requirements of any professional user (e.g. physician) and devices which are mass-produced by means of industrial manufacturing processes in accordance with the written prescriptions of any authorized person shall not be considered to be custom-made devices.

Custom-made solutions

Custom-made solutions based on product series are not considered custom-made devices, since they are mass-produced using industrial methods. To this extent, Bauerfeind AG is the manufacturer of the device and accepts the obligations of the manufacturer.

Orthoses

All orthoses from Bauerfeind AG are issued with a CE marking.

Foot orthoses

Orthopedic foot orthoses relieve the pressure on the feet, knees, hips and back. They have a biomechanical effect, helping the foot to function naturally.

Orthotic blanks

Orthotic blanks are preliminary products that are further modified by the medical supply retailer to create a medical device, and therefore are considered custom-made devices within the meaning of the MDR. The party who **modifies the orthotic blank into a custom-made device is the manufacturer within the meaning of the MDR** and must comply with the requirements for custom-made devices.

Orthotic blanks from Bauerfeind AG do not have a CE marking and are brought on the market without this marking as a potential component of custom-made devices. The orthotic blanks must be selected, combined, modified and further processed by a qualified specialist in accordance with the intended purpose and processing instructions of the producer (Bauerfeind AG in this case) along with the requirements based on the diagnosis and the patient's needs.

Finished products, foot orthosis with CE marking

Foot orthoses that directly exhibit a specific, medical intended use and that can be issued directly to a patient after fitting are considered medical devices and are issued with a CE marking. In this case, Bauerfeind AG is the manufacturer of the foot orthoses within the meaning of the MDR.

Supports

All supports from Bauerfeind AG are issued with a CE marking.

Compression stockings

All compression stockings from Bauerfeind AG are issued with a CE marking.

BODYTRONIC measurement technology

The BODYTRONIC 600/610 are not medical products. These devices are subject to EU regulations

2006/42/EC	EC Machinery Directive
2006/95/EC	EC Low Voltage Directive
2004/108/EC	EMC Directive

Digital applications/apps

Apart from the above products, Bauerfeind has also brought various apps on the market. The therapy apps are medical devices within the meaning of the MDR and are classified in compliance with CE standards. For their precise classification, we refer to the respective instructions for use.

6 Supplementary notes regarding inspection obligations

Formal inspection obligations

You can find the CE marking on the product packaging, the instructions for use and directly on the product.

The UDI (Unique Device Identification) marking is provided by means of a data matrix code on each packaging label.

Instructions for use are enclosed in the packaging for each medical device.

For apps, all necessary information can be accessed under "MORE".

You can download the CE declaration of conformity for our medical devices from our website

Transport and storage

You can find information about the transport and storage conditions on the product packaging and in the instructions for use.

Market monitoring

If you have reason to suspect that a product does not comply with the regulations of the MDR, please contact one of the contacts below immediately.

Traceability

Traceability is ensured by means of the UDI marking. Information about the material number, production date, date of manufacture and expiration date is stored in the data matrix code and also indicated in plain text on the label.

Contact for notifications and queries:

Bauerfeind AG Sales

Contact:

E info@bauerfeind.com

P +49 36628 66-1000

F +49 36628 66-1999

Person responsible for regulatory compliance (Art. 15, MDR)

Contact:

E regulatory.affairs@bauerfeind.com

P +49 36628 66-1000

F +49 36628 66-1999

Contact: Ines Exner

Head of Healthcare

Contact:

E regulatory.affairs@bauerfeind.com

P +49 36628 66-1000

F +49 36628 66-1999

Contact: Jürgen Baden