# Good to know

## Consignment warehouse

Goods from the consignment warehouse are considered to have been placed on the market and can still be sold after May 2021 – for more information see eurocom FAQ point 4.

## Sell-off limit period

Goods that are placed on the market before 25 May 2021 may be sold. You may, in some cases, receive goods with our previous identifying label. They have already been brought onto the market but are a new product and meet the requirements of Article 120, Item 4 of the MDR (sell-off limit period). The goods may therefore be sold up until 26 May 2025 unless they expire before this date - see also eurocom FAQ point 3.

## What are the rules after 25 May 2021 for products with “old” labels?

You may still have products with “old” labels in circulation within your company or in your warehouse after 25 May 2021. This does not have any impact on the safety, performance or quality of the products. These products may still be placed on the market and can be sold up until 26 May 2025, as long as their shelf life permits this.

## Blank insoles from Footcare

The blank insoles that we provide are considered primary products. Blank insoles only become medical devices after the medical supply store has executed the required processing.
medi is happy to support you in fulfilling these requirements. Just get in touch and we'll be there for you.

## Shelf life

All medi products have an expiration date. Manufacturers are obliged to state a clear expiration date for all products, indicating the exact period within which the product can be used safely. The expiration date must at minimum contain the month and year in which the medical aid will expire.

Shelf life of orthopaedic medical aids:
Orthopaedic medical aids also have a limited shelf life. Stability tests have been executed on medi’s orthopaedic medical aids in order to ensure that they are safe to use before the expiration date printed on them.

The hourglass on the label of the packaging shows its shelf life. It is essentially composed of the storage period plus the period of use.

What does that mean for medical compression stockings, for example? You may only hand over the product if the expiration date is at least six months away when it is handed over.

If you receive goods with the old label from us after 25 May 2021, then these are also new goods that have already been brought onto the market before the cut-off date. These may still be sold up until 26 May 2025, if the expiration dates permit this.

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# What does the MDR mean for me?

medi supports you in dealing with MDR requirements

Valid May 26th 2021

medi. I feel better.

# How to deal with MDR requirements – The most important points for you

medi is a manufacturer of medical aids which holds its headquarters in Germany. All products that medi represents as a manufacturer have been classified under the lowest risk class (risk class I).

Manufacturers that make risk class I medical devices are authorised to check the conformity of their products and issue a declaration of conformity themselves in accordance with Annex VIII of the MDR. Thus they are independent of any current shortages with regard to the notified bodies.

The following points not only apply for all products manufactured by medi but also for all products that have been placed onto the market by medi.

1

**The factory symbol on medi product packaging indicates that medi is the manufacturer of the product.**

The obligations that apply for you under the MDR can be split into due care obligations, testing obligations and information obligations.

## Due care obligation

Distributors must ensure that they comply with the applicable requirements of the MDR with due care.

## Testing obligations – Testing before provision to market

Under the directives of the MDR, distributors are obliged to check specific information from the manufacturers. We have summarised this information from the MDR for you in the following ((EU Regulation 2017/745) **eur-lex.europa.eu/eli/reg/2017/745/oj?locale= de**).

A sampling procedure can be used for taking inspection samples. As medi products have the lowest risk class, a small sample test at maximum time intervals is sufficient. The inspection and determination of the time intervals shall be executed by the distributor.

### Does the product have a CE marking and does it have a valid declaration of conformity?

All medical products from medi have a CE marking.

2

**The CE marking can be found on our packaging, on the instructions for use and on the product itself.**

3

**MD** **The MD symbol identifies a product as a medical device.**

- medi guarantees that EU declarations of conformity have been issued for the medical devices that have been placed on the market by us. In order to facilitate handling for you, we have also provided you with a general declaration on our website. We would be delighted to send you digital declarations of conformity for individual products upon request.
- The general declaration of conformity can be found on our homepage at: **medi.biz/zertifikate**

### Is all the information delivered with the product in line with the requirements (Annex I, Chapter III, Item 23, Label and Instructions for Use)?

All information mentioned in this paragraph has been checked by medi and is, insofar as is required, shown in the instructions for use, on the packaging, on the product, on the labels or, if required, in the leaflets included.

### Does the product come from a non-EU country and is it therefore imported?

**If the answer is yes, check that the importer is stated, along with their name and full address, on the packaging or on the included document. Here, it must be ensured that the information from the manufacturer is not covered up or made illegible by the information from the importer.**

All products that you acquire from medi have either been produced by or distributed by medi. This means that the aforementioned requirements have been checked by medi. Therefore, there is no need for any further action on your part.

### Is a UDI code (Unique Device Identifier) applied to the product or packaging?

**The UDI code will first become a requirement for risk class I medical devices from 26 May 2025.**

As the UDI code can supply you with valuable information, medi has already implemented this process and now provides you with support in fulfilling the the device traceability obligation, as well as in the fast and simple documentation of data. Switching to UDI also offers you the opportunity to standardise your inventory management systems. From now, you will receive more and more products with UDI codes from us (GS-1 format).

3

UDI MD (01)04051526391239 (10)202001 (17)230701 (11)200101

**The UDI code supplies the following data:**

- Shelf life
- LOT number (= batch number)
- Production date
- Article number
- Information on who the manufacturer of the product is

### Compliance with the storage and transportation conditions stated by the manufacturer

medi's medical devices are to be always stored in a dry location and kept out of direct sunlight. Therefore there are no further control or documentation obligations for you.


**We're always happy to help: Should you have any doubts or questions on the product, please don't hesitate to contact your medi customer service team. Our team is ready to help you out at telephone number +49 (0)921 912-111.**

## Information obligations – Monitoring after placement on the market (traceability)

This includes forwarding information and cooperating with manufacturers, their authorised representatives, importers and the responsible authorities.

This means that every distributor is obliged to forward information on customer complaints and customer reports, recalls and withdrawals, suspected incidents and questions on product conformity to medi.

### There are specific obligations for:

**Traceability**
Distributors work together with the manufacturers in order to ensure an appropriate level of traceability. This includes information on all manufacturers, importers, authorised representatives and distributors that you have directly received products from or have directly handed products over to. Direct supply of products to other institutions (such as clinics, for example), healthcare centres or other representatives of the healthcare professions must also be documented.
**Supplying products to patients does not require traceability.**

**Complaints book**
Distributors are obliged to keep a register of complaints and reports from representatives in healthcare professions, patients and users. They keep the manufacturer up-to-date via this complaints book and provide required information when requested to do so. Suspected incidents must also be reported to the manufacturer immediately, as always.

For medical devices in risk class I, only severe cases, such as death or a persistent or significant disability or defect, must be reported to the manufacturer.

**Non-conformity of products**
If the distributor establishes or is of the opinion that a product that they have already placed on the market does not meet the requirements of the MDR, the distributor must inform the manufacturer immediately. If the product poses a serious risk in the distributor's opinion, the distributor must also inform the responsible authorities immediately. If the product has not yet reached the market and non-conformity has been established, the distributor is prohibited from providing the product until it complies with the MDR.