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# THE NEW MEDICAL DEVICE REGULATION (MDR) & THE OBLIGATIONS FOR DISTRIBUTORS

# Customer information on the new European Medical Device Regulation (MDR)

The Regulation (EU) 2017/745 (Medical Device Regulation, short MDR) is the new EU regulation on medical devices which came into force in May 2017 and was planned to be applied from May 26, 2020. Due to the Covid-19 pandemic, the application of the MDR has been postponed by one year until May 26, 2021.

The new regulation is intended to improve the quality, safety and reliability of medical devices. A central requirement of the MDR is that the duties, tasks and responsibilities between manufacturer and distributor of the products are clearly defined. This includes, for example, defining the roles between manufacturer and distributor and their relationship to each other, ensuring product traceability and maintaining appropriate documentation.

The effective date of the MDR has been postponed - nevertheless ANITA Dr. Helbig is well prepared for the new Medical Device Regulation. In implementing the MDR requirements we have made them as practical, simple and transparent as possible for both parties – for us as a manufacturer and for our distribution partners.

In order to make your life easier, we have summarised the changes (e.g. on our packaging) and the obligations for distributors (which can be found in article 14 of the MDR) in this paper.

# Obligations for distributors before making a product available on the market

| MDR obligation | How ANITA implemented the obligation |
|---|---|
| Distributor must verify whether the product has a CE mark. | Our products have a CE mark.<br>You can find it on the product hangtag, the label on our breast forms or the label on the packaging. |
| Distributor must verify whether an EU declaration of conformity has been issued for the product. | EU declarations of conformity are available on our website for each product group.<br>https://www.anita.com/en/company/anita-experience/quality-standards.html |
| Distributor must verify whether the product has been provided with a label and instructions for use. | Our medical devices come with an MDR conform label and instructions for use. |
| Information obligations:<br><br>Procedure if distributor has reason to believe that a device does not conform with the MDR, the distributor is obliged to:<br><br>• not make the product available on the market<br>• inform the manufacturer<br>• in case the device might pose a serious risk or is a counterfeit the distributor shall additionally inform the responsible authority | Information obligations:<br><br>Procedure if distributor has reason to believe that a device is not conform with the MDR, the distributor is obliged to:<br><br>• not make the product available on the market<br>• inform ANITA Dr. Helbig GmbH<br>• in case the device might pose a serious risk or is a counterfeit the distributor shall inform the responsible authority |
| Distributor must comply with storage and transport conditions according to manufacturer's specifications | Our storage suggestions include:<br><br>• Protect from sunlight<br>• Store in a dry place<br><br>We do not have any specific tranport conditions for our products. |

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# Obligations for distributors after making a product available on the market

| MDR obligation | How ANITA implemented the obligation |
|---|---|
| Information obligations:<br><br>The same information obligations apply as before making a product available on the market | Information obligations:<br><br>The same information obligations apply as before making a product available on the market |
| Procedure in case of non-conformity:<br><br>• Immediate notification to manufacturer<br>• In case of serious risk or counterfeiting, the relevant responsible authority in all countries where the distributor has made the products available must also be informed<br>• Obligation to cooperate on corrective actions with the manufacturer and, if applicable, the authority | Procedure in case of non-conformity:<br><br>• Immediate notification to ANITA Dr. Helbig GmbH<br>• In case of serious risk or counterfeiting, the relevant responsible authority in all countries where the distributor has made the products available must also be informed<br>• Obligation to cooperate on corrective actions with ANITA Dr. Helbig GmbH and, if applicable, the authority |
| Procedure in case of feedback from the market:<br><br>• Complaints or reports of suspected incidents from the market must be immediately forwarded to the manufacturer<br>• A register of surveillance measures (complaints, non-compliant products, recalls and withdrawals) must be kept and its contents must be made available at the request of the manufacturer/responsible authority<br>• Samples of the product must be made available free of charge to the competent authorities on request | Procedure in case of feedback from the market:<br><br>• Complaints or reports of suspected incidents from the market must be immediately forwarded to ANITA Dr. Helbig GmbH<br>• A register of surveillance measures (complaints, non-compliant products, recalls and withdrawals) must be kept and its contents must be made available at the request of ANITA Dr. Helbig GmbH / responsible authority<br>• Samples of the product must be made available free of charge to the competent authorities on request |

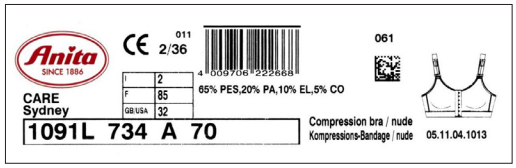
# Timeline for MDR obligations for distributors

- Obligations for distributors apply from May, 26 2021
- Sales period for older products (see Art. 120 para. 4 MDR): distributors can still make products available on the market until 27.05.2025 under the following conditions:
  - products have been placed on the market by the manufacturer (= ANITA Dr. Helbig GmbH) before 26.05.2021 and
  - that these products conform with the previous law, the MDD Directive 93/42/EEC for medical devices

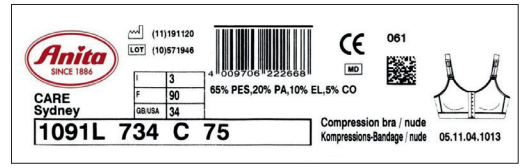
# How Distributors can recognise that a product complies with the new MDR requirements

- Distributors can identify MDR-compliant products by the adapted markings on labels and packaging
  Example of old and new packaging label:

## old




## new




- During the transition period between the MDD and new MDR, older products (bought before 26.05.2021) may also be made available on the market as MDR conform products as long as they conform with the MDD Directive.
- The distributor's obligation to provide proof of MDR-compliant products is fulfilled by the proof of the delivery documents (contain delivery date of products) and the additional markings on product/packaging.

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# New markings on labels and packaging

| Icon | Explanation |
|---|---|
|  | Date of manufacture:<br>From the date of validity of the MDR, products must contain a manufacturing or expiry date. Our Recovery Care and other textiles will carry a manufacturing date. |
|  | Production lot number:<br>Symbol is displayed before the production lot number |
|  | The symbol „MD“ stands for Medical Device – this symbol is displayed to indicate that the product is a medical device. |
|  | Single patient - multiple use: The product can be used several times by one patient only. |

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