Implementation of the Medical Device Regulation (MDR)

*Customer Information & obligations for distributors*

The Regulation (EU) 2017/745 (Medical Device Regulation, short MDR) is the new EU regulation on medical devices, this regulation is in force since May 26, 2021.

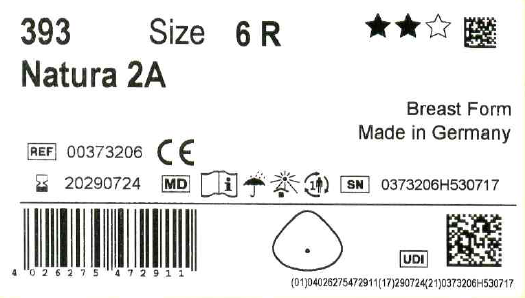
The regulation is intended to improve the quality, safety and reliability of medical devices. A central requirement of the MDR is that the duties, tasks and responsibilities between manufacturer and distributor of the products are clearly defined. This includes, for example, defining the roles between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

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.

We have summarized the changes (e.g. on our packaging) and the obligations for distributors (which can be found in Article 14 of the MDR).

1. **How can you recognise that a product complies with the MDR requirements?**

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



* During the transition period between the MDD (previous medical device directive 93/42/EEC) and new MDR, MDD-compliant products (bought before 26.05.2021) may also be made available on the market.
* 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.

1. **How can you recognise that an IFU complies with the   
   new MDR requirements?**

All Amoena Instructions for use comply with the new MDR requirements.

You can recognise the conformity by keyword such as CE sign, intended purpose, indication, contraindication, instructions for a safe use, special instructions, disposal instructions, reporting obligation, warranty, manufacturer, print date, ID number etc.

1. **Obligations for distributors before making a product available on the market**

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| **MDR obligation** | **How Amoena implemented the obligation** |
| Distributor must verify whether the product has a **CE mark.** | Our products have a CE mark.  You can find it on the product hangtag, the label on our breast forms or the label on the packaging.  Example (label on our breast forms): |
| Distributor must verify whether an **EU declaration of conformity** hasbeen issued for the product. | EU declarations of conformity are available on our website for each product group. |
| Distributor must verify whether the product has been provided with a **label and instructions for use** in the right language. | Our medical devices come with an MDR conform label and instructions for use in in the following languages:  DE, ENG, FR, NL, DK, NO, SE, IT, ES, CZ, CN, ARAB, PL, FI, RU, GR, JP |
| **Information obligations:**  **Procedure if** distributor has reason to believe that a **device does not conform** with the MDR, the distributor is obliged to:   * **not make the product available** on the market * **inform** the manufacturer * in case the device might pose a **serious risk** or is a counterfeit the distributor shall additionally **inform the responsible authority** | Procedure if distributor has reason to believe that a device is not conform with the MDR, the distributor is obliged to:   * not make the product available on the market * inform Amoena, spol. s r.o. * 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 specifications include:   * Protect from sunlight   Computergenerierter Alternativtext:   * Store in a dry place   Computergenerierter Alternativtext:  We do not have any specific transport conditions for our products. |

1. **Obligations for distributors after making a product available on the market**

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| **MDR obligation** | **How Amoena implemented the obligation** |
| **Information obligations:**  The same information obligations apply as before making a product available on the market | **Information obligations:**  The same information obligations apply as before making a product available on the market |
| **Procedure in case of non-conformity:**   * Immediate notification to manufacturer * 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 * Obligation to cooperate on corrective actions with the manufacturer and, if applicable, the authority | **Procedure in case of non-conformity**   * Immediate notification to Amoena, spol. s r.o. * 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 * Obligation to cooperate on corrective actions with Amoena, spol. s r.o. * and, if applicable, the authority |
| **Procedure in case of feedback from the market:**   * Complaints or reports of suspected incidents from the market must be immediately forwarded to the manufacturer * 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 * 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:**   * Complaints or reports of suspected incidents from the market must be immediately forwarded to Amoena, spol. s r.o. * 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 Amoena, spol. s r.o. / responsible authority * Samples of the product must be made available free of charge to the competent authorities on request |

1. **Timeline for MDR obligations for distributors**

* Obligations for distributors apply since May, 26 2021
* Sales period for MDD compliant 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 (=Amoena Medizin-Orthopädie-Technik GmbH) **BEFORE** 26.05.2021 and
* that these products conform with the previous law, the MDD Directive 93/42/EEC for medical devices
* **What happens with goods in your warehouse after May 26th?**

Products with old labels may:

* be sold by you as a specialist retailer until May 2025,
* as long as the expiry date is not exceeded before then.

This also applies to products that arrived at your consignment warehouse before 26 May 2021. These are considered to have been placed on the market and do not need to be relabelled.

1. **Markings on labels and packaging (Overview)**

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| **Icon** | **Explanation** |
| Computergenerierter Alternativtext: | Expiration date:  From the date of validity of the MDR, products have to contain a manufacturing or expiry date. Our Breast Forms, Form Care and some Recovery Care products carry an expiry date. The expiry date is determined on the basis of shelf life studies.  Expired products may no longer be sold. |
|  | Date of manufacture (= shipping date):  From the date of validity of the MDR, products must contain a manufacturing or expiry date. Our Recovery Care and other Textiles carry a manufacturing date. |
| Computergenerierter Alternativtext: REF | Reference number:  Symbol is displayed before the article number |
| Computergenerierter Alternativtext: | Serial number:  Symbol is displayed before the serial number |
| Computergenerierter Alternativtext: | Production lot number:  Symbol is displayed before the production lot number |
| Computergenerierter Alternativtext: | The symbol "MD" stands for Medical Device – this symbol is displayed to indicate that the product is a medical device. |
| Computergenerierter Alternativtext: | Single patient - multiple use: The product can be used several times by one patient only. |
| Computergenerierter Alternativtext: | Read more information in the Instructions for use |
| Computergenerierter Alternativtext: | If the packaging is damaged, the product must not be used |
|  | Products under the responsibility of Amoena GmbH (manufacturer) can be recognized by our address behind a black factory symbol on the label or packaging |
| Computergenerierter Alternativtext: | Protect the products from sunlight |
| Computergenerierter Alternativtext: | Store the products dry |
|  | UDI Code |