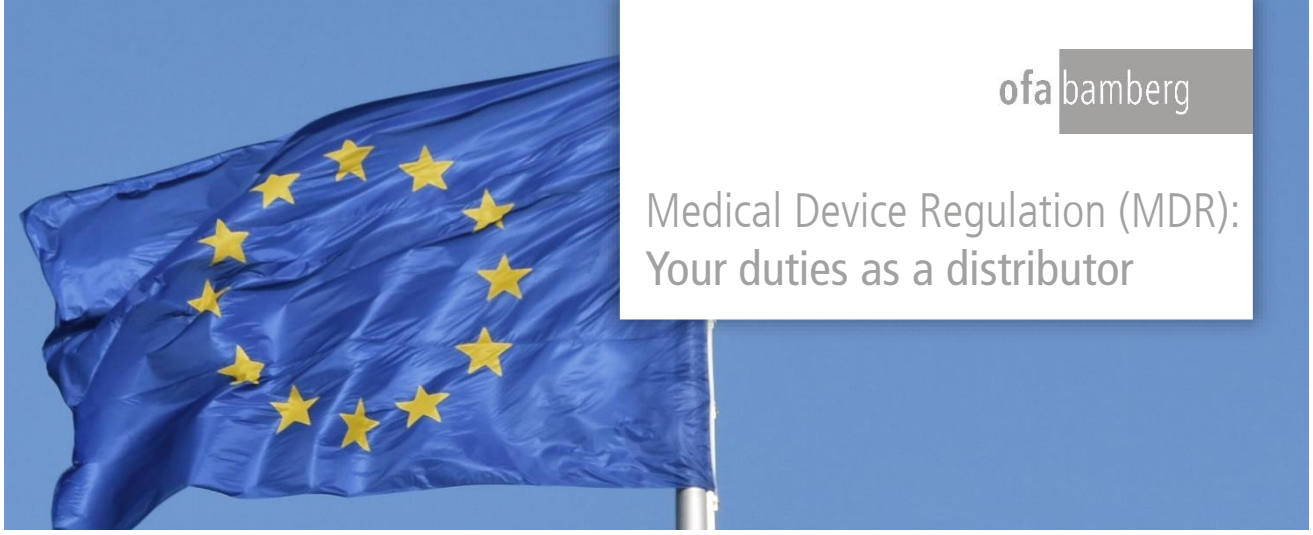

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Medical Device Regulation (MDR): Your duties as a distributor

Please note

This brief overview cannot replace **a further discussion of the complete text of the European Medical Devices Regulation (MDR).** For more detailed questions, the relevant articles in the regulation should be consulted - only those are legally binding.

The information listed here is **specific to Ofa Bamberg products**. Obligations of distributors with regard to products of other manufacturers with deviating, individual specifications or products of classes 1r/m/s or higher are not taken into account here.

All information has been carefully compiled and checked but does not replace comprehensive legal advice; **liability and warranty claims with regard to the contents are excluded.**

What are the obligations of the specialized medical supply trade in its role as a distributor?

General Duty of Care → Article 14 (1) MDR

Inspection obligations regarding the product: → Article 14 (2) MDR

- CE marking
- The name or trade name of the device
- Indication of what the product is about
- Reference to medical device
- Name and address of the manufacturer
- Expiry date
- Storage and handling instructions
- UDI (for class 1 only mandatory from 2025)

Inspection obligations regarding the instructions of use → Article 14 (2b) MDR → Article 10 (11) MDR

- Name/trade name of the product
- Name and address of the manufacturer
- Information on storage and handling, which must be adhered to
- Intended use
- Indications, contraindications, side effects, residual risks
- Information on use and care
- Issue / revision date of the instructions of use
- Information on the obligation to report

Procedure in case of non-compliance: → Article 14 (4) MDR → Article 14 (5) MDR

- If a product does not comply with the requirements, it must not be dispensed to patients!
- The manufacturer must be informed. If the product poses a serious risk, the competent authorities must also be informed (DE→ BfArM)
- Regarding possible corrective measures, distributors are obliged to cooperate with manufacturers and authorities.
- Distributors must keep a register of complaints, recalls, withdrawals and non-conforming products.

Further information about the MDR can be found on the Ofa partner portal at **portal.ofa24.de/en/mdr**

For specific questions, please do not hesitate to contact your Ofa consultant or export@ofa.de

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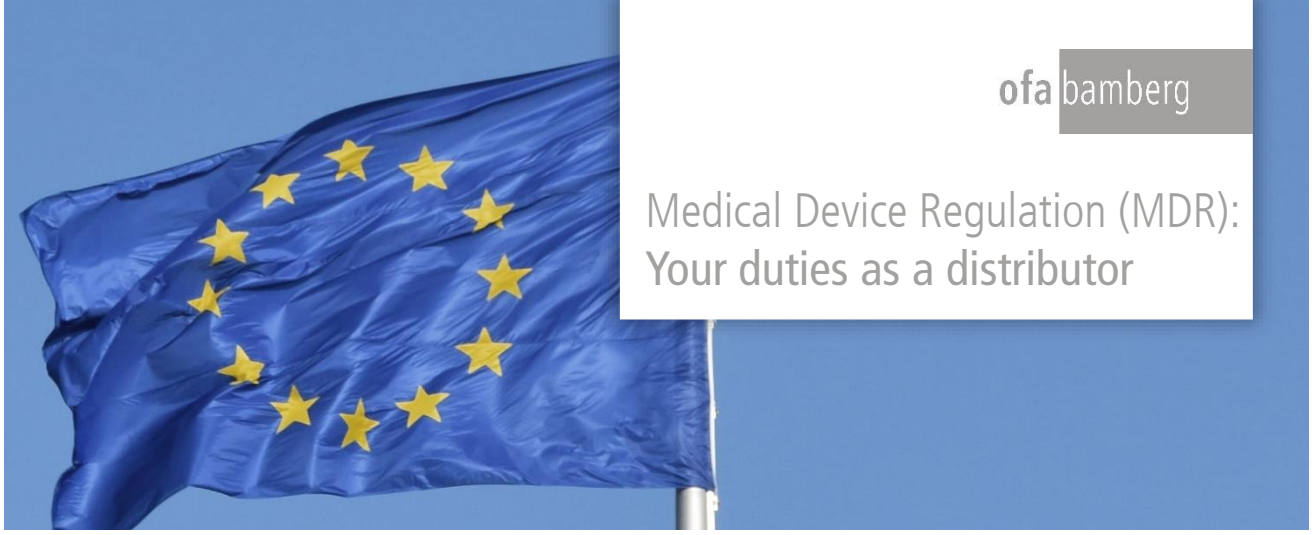

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Medical Device Regulation (MDR): Your duties as a distributor

Further obligations of the specialized medical supply trade in its role as a distributor

Traceability of products:

Over a period of 10 years, the distributor must be able to provide the competent authorities with information on the following points:

- To whom was the product supplied? (all economic operators / health care facilities / health care professionals; not patients!)
- From whom was the product obtained?

→ Article 25 MDR

Advertising and illustrations:

- When advertising or providing information on products, distributors may only use illustrations and information intended by the manufacturer for the product in question

→ Article 7 MDR

Ofa Bamberg helps to shape the future

As a member of the Spectaris Industrial Association and the Deutsche Gesellschaft für interprofessionelle Hilfsmittelversorgung e. V. (DGIHV), Ofa Bamberg is intensively involved in the association's work - the aim: to develop, together with representatives from politics, leading associations, trade unions, science and industry, clear paths and concrete action plans for the implementation of the MDR.

MITGLIED BEI SPECTARIS
Deutscher Industrieverband für Optik, Photonik, Analysen- und Medizintechnik

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