ofa bamberg

Checklist:
Your inspection obligations

What do you, as a distributor, have to check before dispensing a product?

Inspection obligations regarding the product → Article 14 (2) MDR		CE marking → CE
		Name/trade name of the product
		Indication of what the product is about
		Reference to medical device → MD
		Name and address of the manufacturer →
		Expiry date / manufacturing date → /
		Storage and handling instructions →
		UDI (for class 1 only mandatory from 2025)
Inspection obligations regarding the instructions for use → Article 14 (2b) MDR Tip: Points 1-3 you find on the front and back cover of the instructions of use, the other inside.		Name of the product
		Name and address of the manufacturer
		Issue/revision date of the instructions of use
		Storage and handling instructions
		Intended use
		Information on care
		Information on use
		Indications
		Contraindications
		Side effects
		Residual risks
		Information on the obligation to report

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

Ofa Bamberg GmbH
Laubanger 20
96052 Bamberg, Germany

Status: 03 May 2021