

Amoena Medizin-Orthopädie-Technik GmbH
Kapellenweg 36 · 83064 Raubling · Germany

Amoena
Medizin-Orthopädie-Technik GmbH
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Declaration of Conformity for Medical Devices according to Regulation (EU) 2017/745

Company name / manufacturer

Amoena Medizin-Orthopädie-Technik GmbH
Kapellenweg 36, 83064 Raubling, Germany
SRN (Single Registration Number):
DE-MF-000009133

Product details

Amoena Lingerie
Mastectomy bras for wearing breast prosthesis
Basis UDI-DI: 4026275Y063099L29
CuraLymph Comfort
products for lymph care
Basis UDI-DI: 4026275M030499C3QC
CuraLymph Compression
products for lymph care
Basis UDI-DI: 4026275M030499C4QE
exact article descriptions and article numbers see
appendix 230307 DoC CuraLymph CZE

Classification according to Annex VIII

Class I

Declaration

We declare under our responsibility that the following listed medical devices according to Annex I of Regulation (EU) 2017/745 (MDR) meet all applicable basic safety and performance requirements. The conformity assessment was carried out in accordance with Annex IV of the MDR Regulation EU 2017/745.

Our quality management system is certified according to
EN ISO 13485:2016 medical devices quality management systems requirements for regulatory purposes.

Raubling, 28.11.2023

Oliver Dörner
CEO



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Geschäftsführer:
Oliver Dörner
Stephanie Bauch
Sitz der Gesellschaft: Raubling
Amtsgericht Traunstein HRB 9000
Ust-ID: DE 176 896 546

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<i>item</i>	<i>short description</i>	<i>description</i>	<i>item number</i>	<i>originally CE- marked</i>
Leslie SB	Leslie SB	products for lymph care/ Lingerie	44847	01.07.2022
Linda SB	Linda SB	products for lymph care/ Comfort	44811 44936	14.09.2022 24.11.2023
Liane Top	Liane Top	products for lymph care/ Comfort	44812 44934	14.09.2022 24.11.2023
Lymph Flow SB FC	LymphFlow SB FC	products for lymph care/ Compression	44814 44816	10.01.2023 10.01.2023
Lymph Flow Long SB FC	LymphFlowLongSBFC	products for lymph care/ Compression	44813 44815	10.01.2023 10.01.2023
Lymph Flow Pressure Pad	Lymph Flow Pressure Pad	products for lymph care/ Compression	020	10.01.2023