



## CERTIFICATE



This is to certify that the company

## Amoena Medizin-Orthopädie-Technik GmbH

Kapellenweg 36 83064 Raubling Germany

has implemented and maintains a Quality Management System.

Scope:

Development, production and sales of breast forms and partial shapers following breast surgery and pocketed lingerie, swimwear and accessories under the brand Amoena. Development, production and sales of silicone scar patches and compression garments under the brand AmoCura

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

## DIN EN ISO 13485 : 2016 + AC : 2017-07 EN ISO 13485 : 2016 + AC : 2016 ISO 13485 : 2016

385002 MP2016

170777418

2022-01-21

2025-01-20

2022-01-10

Certificate registration no.

Certificate unique ID

Effective date

Expiry date

Frankfurt am Main

## **DQS Medizinprodukte GmbH**

We leuro

Sigrid Uhlemann Managing Director

DAKKS Deutsche Akkreditierungsstelle D-ZM-16021-01-00

Dr. Thomas Feldmann Head of Certification Body



August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de