



# 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 and swimwear under the brand Amoena.

Development, production and sales of wheelchair cushions (systems) for antidecubitus-prophylaxis under the brand Amovida.

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

Certificate registration no. 385002 MP2016

Certificate unique ID 170719713

Effective date 2019-01-21

Expiry date 2022-01-20

Frankfurt am Main 2019-01-21



### DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Managing Director

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](mailto:medical.devices@dqs-med.de)