

# Certificate

We hereby certify the company

**ANITA Dr. Helbig GmbH**  
**Grafenstraße 23**  
**83098 Brannenburg**  
**Germany**



with the sites listed in the attachment the introduction and application of a

## **Quality management system according to EN ISO 13485**

in the scope

development, production and distribution of breast forms and accessories as well as corsetry and swimwear with a medical purpose

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016  
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2024-11-16  
Valid until 2027-11-15

Registration No. D1442700009  
Report No. P24-01010-305935

Berlin, 2024-11-11

  
Certification Body



Sites included in the certification:

Location	Scope
ANITA Dr. Helbig GmbH Grafenstraße 23 83098 Brannenburg Germany	Development, production and distribution of breast forms and accessories as well as corsetry and swimwear with a medical purpose
Anita Dr. Helbig GmbH Natalis-Obwexer-Straße 15 9971 Matri i. Osttirol Austria	Production of breast forms and accessories

Berlin, 2024-11-11



Certification Body