

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 2025-12-11
Valid until 2027-11-15

Registration No. D1442700011
Report No. P25-00791-339023

Berlin, 2025-12-11


Certification Body



Sites included in the certification:

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

Berlin, 2025-12-11



Certification Body