

CERTIFICATE

Berlin Cert

Prüf- und Zertifizierstelle für Medizinprodukte GmbH



hereby certifies that

dantschke Medizintechnik GmbH & Co. KG

Apelsteinallee 3, 04416 Markkleeberg, Deutschland

has implemented and uses a quality management system for the following scope of application

Design, Production, Sales and Service of medical devices for ENT-diagnostics and therapy as well as trade of accessories

The audit report no. B-23-079-S-RZ provided confirmation that the requirements in the standard

DIN EN ISO 13485:2021

EN ISO 13485:2016 + AC:2018 + A11:2021

Medical devices - Quality management systems
Requirements for regulatory purposes

have been fulfilled.

Issued : 06.09.2023

Valid from: 06.09.2023

Valid until: 05.09.2026

BERLIN CERT
AFNOR Group
Dipl.-Ing. Martin Tettke
Signature of authorised representative

