CERTIFICATE

Berlin Cert

Prüf- und Zertifizierstelle für Medizinprodukte GmbH



hereby certifies that

HIDREX GmbH

Otto-Hahn-Str. 12, 42579 Heiligenhaus, Deutschland

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

In-house and third-party (OEM) development, production, service and sales of medical devices for stimulation and for the electronic compensation of disabilities as well as import of the medical device "Feeding Device"

The audit report no. B-23-017-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: 23.08.2023

Valid from: 23.08.2023

Valid until: 28.07.2026







