

# CERTIFICATE

Number: 2214099

The management system of the organization(s) and locations mentioned on the addendum belonging to:

**Heinz Kurz GmbH**

Tübinger Strasse 3  
72144 Dusslingen  
Germany

Manufacturer Facility Identifier F005667

Conforms with the following standard and regulatory requirements:

## ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 665/2022, 551/2021 and 67/2009

Canada: Medical Devices Regulations - Part 1- SOR 98/282

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act

United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:

Design and development, manufacturing and distribution of medical implants for otology, rhinology, laryngology and ophthalmology and corresponding instruments.

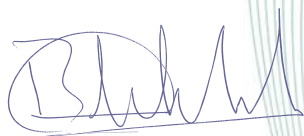
Certificate expiry date: 2027-01-01

Certificate effective date: 2025-02-04

Certified since: 2021-12-03

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.M. McKenzie  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed.

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:  
<https://www.dekra-checkme.com/org>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.





# ADDENDUM

To certificate: 2214099

The management system of the organization(s) and/or location(s) of:

## Heinz Kurz GmbH

Tübinger Strasse 3  
72144 Dusslingen  
Germany

Certified organization(s) and/or locations:

Different scope

Heinz Kurz GmbH  
Im Steinig 75/1  
72144 Dusslingen  
Germany  
Facility Identifier F005667

Manufacturing, Final packaging (insertion of IFU) after incoming inspection after sterilization, final goods storage and delivery storage for medical implants and instruments

Addendum expiry date: 2027-01-01  
Addendum effective date: 2025-02-04