

CERTIFICATE

Number: 2247210

The management system of:

PATH medical GmbH

Landsbergerstrasse 65
82110 Germering
Germany

Manufacturer Facility Identifier F004413

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

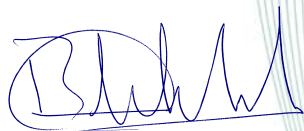
Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 665/2022, 551/2021 and 67/2009
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW Ministerial Ordinance 169, Article 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, Development, Manufacture, Servicing, Installation and Distribution of medical instruments for screening and diagnostics in the field of audiology and otorhinolaryngology (ORL) including vestibular and neurological applications.

Certificate expiry date: 2028-11-01
Certificate effective date: 2025-11-01
Certified since: 2020-07-09

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Certification Manager

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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.

