CERTIFICATE

Number: 2229417

The management system of:

Technomed Europe

Amerikalaan 71
6199 AE Maastricht Airport
The Netherlands

Manufacturer Facility Identifier F002732

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, and distribution of sterile and non-sterile stimulating and recording electrodes, including EEG electrodes, adhesive electrodes, needle electrodes, probes, surgical instruments, and laryngeal electrodes for neuro-diagnostic examinations; including extension cables; and the distribution of neuro-diagnostic systems for intra-operative monitoring

Certificate expiry date:	2026-05-01
Certificate effective date:	2023-05-01
Certified since:	2020-05-14

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M.A. McKenzie
Certification Manager

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https:/www.dekra-product-safety.com/en/certified-organizations

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM