TÜVUSA

CERTIFICATE

Management system as per

ISO 13485:2016 (MDSAP)

The Auditing Organization TÜV USA, Inc. hereby confirms as a result of the audit, assessment, and certification decision according to ISO/IEC 17021-1:2015, that the organization

Neurovision Medical Products, Inc.
353 Sanjon Road
Ventura, California 93001
United States of America
[Facility ID: F001749]

with the locations according to Annex 1
with products according to Annex 2

operates a management system in accordance with the requirements of ISO 13485:2016 (MDSAP) and will be assessed for conformity within the 3-year term of validity of the certificate for the following jurisdictions:
Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 excluding Part 1.6) – Full Quality Assurance Procedure
Canada: Medical Devices Regulations – Part 1- SOR/98-282.
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68
United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

Scope

Design, Manufacture, Distribution and Service of Laryngeal Surface Electrodes, Nerve Location Devices and Software, Surface Electrodes, Stimulation Instruments, and Surgical Devices used for Nerve Monitoring during Surgery

Certificate Registration No. 24-1611-M
Project no. 23-4103 RC CSA

Valid from 2024-05-30
Valid until 2027-05-29
Initial Certification: 2018-10-26

Auditing Organization TÜV USA, Inc.

Salem, NH 2024-05-30, Edition 1

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TUV USA, Inc. is recognized under the Medical Device Single Audit Program

The validity of this certification document can be obtained by contacting the TUV USA, Inc, office. Tel: 001-603-870-8023 (option 1), Email: medical-usa@tuv-nord.com

Annex 1

to Certificate Registration No. 24-1611-M

ISO 13485:2016 (MDSAP)

Neurovision Medical Products, Inc.
353 Sanjon Road
Ventura, California 93001
United States of America
[Facility ID: F001749]

Validity of Annex depends on the validity of the main certificate.

Certificate Registration No.	Location	Scope
24-1611-M [Facility ID: F001749]	Neurovision Medical Products 353 Sanjon Road Ventura, California 93001 United States of America	Design and Development, Administration and Service
24-1611-M-001 [Facility ID: F001749]	Neurovision Medical Products 4837 McGrath, Suite B, Ventura, California 93001 United States of America	Manufacture, Distribution

End of List

Certificate Registration No. 24-1611-M
Project no. 23-4103 RC CSA

Valid from 2024-05-30
Valid until 2027-05-29
Initial Certification: 2018-10-26

Auditing Organization TÜV USA, Inc.

Salem, NH 2024-05-30, Edition 1

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Annex 2

to Certificate Registration No. 24-1611-M

ISO 13485:2016 (MDSAP)

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Validity of Annex depends on the validity of the main certificate.

Products	UMDNS	GMDN
Nerveana System with EMGView Upgrade and Muting Sensor	13-775	35723
TadPole Hydrogel Electrode	11-441	61020
DryTouch Suction Stimulator Probe	15-237	61088
Scorpion Stimulation Instruments - Single Use	15-237	61089
Scorpion Stimulation Instruments - Reusable	15-237	61090
Hummingbird Probes	15-237	61089
EMG Needles - Single Use	11-441	11441

Continue on page 2

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Annex 2

to Certificate Registration No. 24-1611-M

ISO 13485:2016 (MDSAP)

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Products	UMDNS	GMDN
Cobra	11-441	61070
Urethral Surface Electrode	11-441	64916
Laryngeal Surface Electrode LSE500 and LSE600 Series	11-441	62208
Stimulation Lead Wire	16-314	61020

End of List

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