

Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **18-1612-M**

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 under MDSAP for Medical Devices Requirements under 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. **USA:** United States: 21 CFR 803; 21 CFR 806; 21 CFR 807 – Subparts A to D; 21 CFR 820.

Neurovision Medical Products, Inc.
353 Sanjon Road
Ventura, CA 93001, USA

Facility ID: **F001749**

Additional sites covered by QM System: **See Annex 1**

List of Products: **See Annex 2**

Scope:

The 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

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.

TUV USA, Inc. (a Member of the TÜV NORD Group)

215 Main Street, Suite 1, Salem, NH 03079, USA

Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com

TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: **19-3756 SA2-SPA**

Certificate Initial Issue Date: **2018-10-26**

Current Cycle Start Date: **2018-10-26**

Certificate Revised Date: **2021-03-22**

Effective Date:

2021-03-11 / ed. 3

Valid Until:

2021-10-25



Bradley Chen
Vice President – Medical, Americas
Medical Products Division
TUV USA, Inc.

Certificate Registration No. : 18-1612-M / ed. 3
Company Name: Neurovision Medical Products, Inc.
Central Office Address: 353 Sanjon Road, Ventura, CA 93001, USA



Location

Scope of Certification

Facility ID: F001749 (Campus)

Headquarters

Neurovision Medical Products, Inc.
353 Sanjon Road
Ventura, CA 93001, USA

Design and Development,
Administration and Service

Site 1

Neurovision Medical Products, Inc.
4411 Dupont Court
Ventura, CA 93003, USA

Manufacture, Distribution

---End of list---

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.
TUV USA, Inc. (a Member of the TÜV NORD Group)
215 Main Street, Suite 1, Salem, NH 03079, USA
Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com
TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: 19-3756 SA2-SPA
Certificate Initial Issue Date: 2018-10-26
Current Cycle Start Date: 2018-10-26
Certificate Revised Date: 2021-03-22

Effective Date:
2021-03-11 / ed. 3

Valid Until:
2021-10-25

Bradley Chen
Vice President – Medical, Americas
Medical Products Division
TUV USA, Inc.

Certificate Registration No. : 18-1612-M / ed. 3
Company Name: Neurovision Medical Products, Inc.
Central Office Address: 353 Sanjon Road, Ventura, CA 93001, USA



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
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---

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.
TUV USA, Inc. (a Member of the TÜV NORD Group)
215 Main Street, Suite 1, Salem, NH 03079, USA
Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: medical-usa@tuv-nord.com
TUV USA, Inc. is an MDSAP Recognised Auditing Organization



Audit Report Reference No.: 19-3756 SA2-SPA
Certificate Initial Issue Date: 2018-10-26
Current Cycle Start Date: 2018-10-26
Certificate Revised Date: 2021-03-22

Effective Date:
2021-03-11 / ed. 3

Valid Until:
2021-10-25

Bradley Chen
Vice President – Medical, Americas
Medical Products Division
TUV USA, Inc.