

Certificate

Certificate No.: Manufacturer: MD 73072470-160

NISSHA MEDICAL TECHNOLOGIES SAS Z.A. des Boutries 12 rue des Cayennes 78700 Conflans Sainte Honorine France

D-U-N-S No.:

39-190-6658

Certification criteria:

ISO 13485:2016

Canada Medical Devices Regulations – Part 1 – SOR 98/282

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D, 21 CFR 821

Scope:

Design and development, manufacture and distribution of pre-wired electrodes, ECG cables, adapter cables and leadwires and leads, pressure cables, SPO2 cables, electrosurgery cables, multiparameter cables.

Manufacture and distribution of non-sterile endoscopy tubing sets.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	73072470/160
Issue Date:	2020-08-06
Effective Date:	2020-08-06
Expiry Date:	2021-12-26

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Certification of Cer: Sebastian Mniszek TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000007216?locale=en or calling 1-888-743-4652.

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DICAL DEVICE SINGLE AUDIT PROGRA

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