

## Certificate

Certificate No.: MD 1743273-1-1

Manufacturer: NISSHA MEDICAL TECHNOLOGIES SAS

23-25 Boulevard de la Paix

95800 Cergy

France

REPs Facility ID: F001612

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.

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.: 73082361-100

 Issue Date:
 2023-05-30

 Effective Date:
 2023-05-30

Expiry Date: 2024-12-26



Certification officer: Daniel Świątko TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality\_marks/9000019981?locale=en or calling 1-888-743-4652.