

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Nissha Medical Technologies SAS

Main Site: 23-25 Boulevard de la Paix

95800 Cergy, France (FIN F007472)

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

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)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable)

The management system is applicable to:

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 and sterile endoscopy tubing sets.

Organization was certified by another Certification Body before 7/25/2024.

Certificate Number:

0182572

Revision Level: 02

Date of Certification Decision:

2026-02-17

Certification Effective Date:

2026-02-17

Certification Expiry Date:

2027-12-26



intertek

A handwritten signature in black ink that reads "Mark Thomas".

Mark Thomas

Executive Vice President

Assurance, Sustainability, AgriWorld & Food

Intertek Testing Services NA, Inc.

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