

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)

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.

Manufacture and distribution of non-sterile endoscopy tubing sets.

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

Certificate Number:

0182572

Revision Level: 00

Date of Certification Decision:

2024-07-25

Certification Effective Date:

2024-07-25

Certification Expiry Date:

2024-12-26





intertek



President, Business Assurance

Intertek Testing Services NA, Inc. 4700 Broadmoor SE, Suite 200 Kentwood, MI, USA, 49512



