

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Nissha Medical Technologies Limited

Main Site: Torbay Business Park, Woodview Road
Paignton, Devon TQ4 7HP United Kingdom (FIN F005188)

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

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
(excluding Part 1.6)

Brazil: RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

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, Development, Manufacture and Distribution of ECG and neutral
electrodes.

Manufacture and Distribution of Medical Chart Recording Paper.

Organization was certified by another Certification Body before 8/21/2025

Certificate Number:

0222714

Revision Level: 00

Initial Certification Date:

2020-03-30

Date of Certification Decision:

2025-08-21

Certification Effective Date:

2025-08-21

Certification Expiry Date:

2026-03-29



A handwritten signature in black ink, appearing to read "Rathin Grover".

Rathin Grover

President, Business Assurance

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

