

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. 665/2022, RDC ANVISA n. 551/2021, 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: 01

Initial Certification Date:

2020-03-30

Date of Certification Decision:

2026-03-16

Certification Effective Date:

2026-03-29

Certification Expiry Date:

2029-03-29



intertek

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