

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Graphic Controls d.b.a. Nissha Medical Technologies, Vermed, Biomedical Innovations

(F000831)

Main Site: 400 Exchange Street, Buffalo, New York, 14204, USA

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

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

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

The design, development, and manufacture of medical recording charts, lead wires, ECG electrode families. Design of defibrillator pads. Repacking and relabeling of tympanostomy tubes.

Certificate Number:

0085640-05

Initial Certification Date:

2018-12-30

Date of Certification Decision:

2023-12-18

Certification Effective Date:

2023-12-18

Certification Expiry Date:

2024-12-29



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Calin Moldovean

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