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: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

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, leadwires, ECG electrode families. Design of defibrillator pads.

Certificate Number:
0085640-02

Initial Certification Date:
30 December 2018

Date of Certification Decision:
02 February 2021

Issuing Date:
02 February 2021

Valid Until:
29 December 2021

ISO 13485:2016 CERTIFICATION™

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

Intertek

Calin Moldovean
President, Business Assurance

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