

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Graphic Controls Acquisition Corp. dba Nissha Medical Technologies

(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

**Revision Level:** 06

**Initial Certification Date:**

2018-12-30

**Certification Effective Date:**

2024-06-06

**Certification Expiry Date:**

2024-12-29



intertek

A handwritten signature in black ink, appearing to read "Calin Moldovean", written over a horizontal line.

**Calin Moldovean**

President, Business Assurance

Intertek Testing Services NA, Inc.  
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