

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Nissha Medical Technologies Limited  
Torbay Business Park  
Woodview Road  
Paignton  
Devon  
TQ4 7HP  
United Kingdom

Facility ID Number: F003427

Holds Certificate No:

**MDSAP 707430**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**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

**Japan:** MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, Development, Manufacture and Distribution of ecg and neutral electrodes.  
Manufacture and Distribution of Medical Chart Recording Paper.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-03-30

Effective Date: 2023-03-30

Expiry Date: 2026-03-29



BSI Group America Inc. is an MDSAP recognised auditing organization

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