

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Sanmina - SCI Israel
Medical Systems Ltd.
5 Haroshet St.
Koren Industrial Park,
Maalot-Tarshiha,
2101802
Israel

Facility ID Number: F005067

Holds Certificate No: **MDSAP 738610**

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 4 - Production Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

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

Contract Manufacture of printed circuit boards, electro-mechanical and optomechanical assemblies and fabrication of metal components.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-09-16

Effective Date: 2025-07-21

Expiry Date: 2027-09-15



BSI Group America Inc. is an MDSAP recognised auditing organization

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