By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Ranfac Corporation
30 Doherty Avenue
Avon
Massachusetts
02322
USA

Facility ID Number: F003107

Holds Certificate No: **MDSAP 701578**

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
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development and manufacture of hypodermic needles, special needles, biopsy needles, contrast medium infusion sets, breast care system, cholangiography catheters, suture grasper, laparoscopic surgery devices, core decompression devices and platelet separator devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-05 Effective Date: 2023-04-14 Expiry Date: 2025-10-03

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

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