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, cholangography catheters, suture grasper, laparoscopic surgery devices and core decompression devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-05-05 Effective Date: 2022-10-04 Expiry Date: 2025-10-03

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

...making excellence a habit.™

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
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