

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Wellspect HealthCare
(a division of Dentsply IH AB)
Aminogatan 1
PO Box 14
SE-431 21 Mölndal
Sweden

Facility ID Number: F000483

Holds Certificate No:

MDSAP 690049

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; 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, manufacture and distribution of sterile single use urinary catheters, urological stoma drainage catheters and non-sterile active and non-active trans-anal irrigation system devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-03-21

Effective Date: 2022-01-03

Expiry Date: 2024-12-14



BSI Group America Inc. is an MDSAP authorized auditing organization

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