

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Wellspect Healthcare  
Aminogatan 1  
PO Box 14  
SE-431 21 Mölndal  
Sweden

Facility ID Number: F000483

Holds Certificate No:

**MDSAP 780139**

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

**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

Design, manufacture and distribution of sterile single use urinary catheters for intermittent catheterization (dilatation/ instillation) and non-sterile active and non-active trans-anal irrigation system devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2023-03-28

Effective Date: 2024-12-15

Expiry Date: 2027-12-14



BSI Group America Inc. is an MDSAP recognised auditing organization

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