By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number: MD 780132

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture (including manufacturing at external sites under contract), sterilization, final inspection and distribution of:
- sterile single use urinary catheters for intermittent catheterization, dilatation, and instillation
- bowel management systems for trans-anal irrigation, including manual and electronically powered variants
- urine management systems for incontinence care

Sterilization by e-Beam irradiation of in-house Wellspect HealthCare and other Dentsply Sirona companies' medical devices, fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2022-11-28
Effective Date: 2024-12-15
Latest Revision Date: 2026-11-16
Expiry Date: 2027-12-14

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Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact:
BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

Certificate No: MD 780132

Location	Registered Activities
Wellspect HealthCare Aminogatan 1 PO Box 14 SE-431 21 Mölndal Sweden	Design, manufacture, sterilization, final inspection 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. Sterilization by e-Beam irradiation of in-house Wellspect HealthCare and other Dentsply Sirona companies' medical devices, fulfilling applicable quality management system requirements within EN ISO 11137-1:2015.
Wellspect Healthcare Kryptongatan 24 43153 Mölndal Sweden	Manufacture and distribution of sterile single use urinary catheters for intermittent catheterization and bowel management systems for transanal irrigation, including manual and electronically powered variants.

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