

# 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  
Möln dal  
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, 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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2022-11-28

Latest Revision Date: 2024-11-20

Effective Date: 2024-12-15

Expiry Date: 2027-12-14

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Certificate No: MD 780132

Location	Registered Activities
Wellspect HealthCare Aminogatan 1 PO Box 14 SE-431 21 Möndal 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 Kryptogatan 24 43153 Möndal Sweden	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.



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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

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