

# 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  
Mölnadal  
Sweden

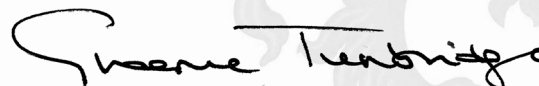
Holds Certificate Number:

**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, urological stoma drainage catheters 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 Medical Devices

Original Registration Date: 2022-11-28

Latest Revision Date: 2023-11-17

Effective Date: 2022-11-28

Expiry Date: 2024-12-14

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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, urological stoma drainage catheters 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 and non-sterile active and non-active trans-anal irrigation system devices. Distribution of sterile urological stoma drainage catheters.



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