

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN 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

Holds Certificate Number:

MD 588584

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, sterilisation, 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.

Provision of an e-beam sterilisation service in accordance with EN ISO 11137-1:2015

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2012-08-17

Latest Revision Date: 2021-12-13

Effective Date: 2021-12-15

Expiry Date: 2024-12-14



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Certificate No: **MD 588584**

Location	Registered Activities
Wellspect HealthCare (a division of Dentsply IH AB) Aminogatan 1 PO Box 14 SE-431 21 Mölndal Sweden	Design, manufacture, sterilisation, 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. Provision of an e-beam sterilisation service in accordance with EN ISO 11137-1:2015
Wellspect HealthCare (a division of Dentsply IH AB) An der Kleinen Seite 8 Elz 65604 Germany	Storage and distribution of sterile single use urinary catheters, urological stoma drainage catheters and non-sterile active and non-active trans-anal irrigation system devices.
Wellspect HealthCare (a division of Dentsply IH AB) Kryptogatan 24 43153 Mölndal 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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