

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 749583 R000

Manufacturer: Wellspect HealthCare (a division of Dentsply IH AB)

Address:

Aminogatan 1
PO Box 14
SE-431 21 Mölndal
Sweden

Single Registration Number: SE-MF-000010048

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-10-07**

Date: **2021-10-07**

Expiry Date: **2026-10-06**

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Device(s)	Risk Classification
U01010501 – Urological Catheters, Nelaton auto-lubricant	Class Is
U01010601 – Urological Catheters, Tiemann auto-lubricant	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.



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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3429252	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

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

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 749583 R000

Date: 2021-10-07

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Oasis Medikal AS Faith Mahallesi 3105 Cad. No 8, Kazan Ankara 06980 Turkey	ETO Sterilization Manufacture Packaging
Wellspect HealthCare Kryptongatan 24 43153 Mölndal Sweden	Manufacture

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