EU Quality Management System Certificate

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

MDR 780135 R001

Manufacturer: Wellspect HealthCare

Address:
Aminogatan 1
PO Box 14
SE-431 21
Mölndal
Sweden

Single Registration Number: SE-MF-000026271

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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2022-10-26**

Current Issue Date: **2026-09-02**

Starting Validity Date: **2026-10-07**

Expiry Date: **2031-10-06**

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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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Gastrointestinal Lavage, Tubes and Sets	Class IIa
Urological Catheters, Nelaton auto-lubricant	Class Is
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
2022-10-26	3785592	Issued – Traceable to MDR 749583
2026-02-26	30664602	Amended – Addition of critical subcontractor for sterilization of water sachets supplied with urological catheters
Current	30776020	Re-Issued – Certificate Renewal

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