EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 737173 R000

Manufacturer: Smith & Nephew Medical Ltd

Address:
101 Hessle Road
Hull
HU3 2BN
United Kingdom

Single Registration Number: GB-MF-000017580

EU Authorised Representative: Smith & Nephew Operations B.V.

Address:
Bloemlaan 2
2132 NP
Hoofddorp
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X 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: **2021-06-07**

Current Issue Date: **2024-11-13**

Starting Validity Date: **2024-11-13**

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

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Skin closure strips	Class IIa
Impregnated gauzes	Class IIa
Adhesive absorbent dressings	Class IIa
Dressings for wounds, sores and ulcerations	Class IIa
Protective devices, lubricants and soothing devices (sprays, gels, fluids and creams)	Class IIa
Surgical Drapes	Class IIa
Adhesive absorbent dressings	Class Is
Fixation dressings	Class Is
Non-adhesive absorbent dressings	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
2021-06-07	3258304	Issued
2021-09-09	3512573	Supplemented – Addition of device category Adhesive film dressings with or without absorbent pad. Supplemented – Addition of device category Skin closure strips. Amended - Addition of critical subcontractors for sterilisation.
2022-03-18	3654158	Supplemented – Addition of device category silicone dressings.

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Date	Reference number	Action
2023-09-08	3852118	Supplemented – Addition of device category Impregnated Gauzes. Supplemented – Addition of device category Protective Devices, lubricants and soothing devices (sprays, gels, fluids and creams). Supplemented – Addition of device category Surgical Drapes. Restricted – Removal of device category Skin Stapler Handle. Amended – Name change of Adhesive film dressings with or without absorbent pad to Adhesive absorbent dressings. Amended – Name change of Silicone dressings to Dressings for wounds, sores and ulcerations. Amended – Name change of Low adherent absorbent dressings, Absorbent Tracheostomy dressings and Non-woven dressings to Non-adhesive absorbent dressings. Amended – Name change of Catheter fixation dressings and Catheter dressings to Fixation dressings. Amended – Name change of Non-woven adhesive dressings to Adhesive absorbent dressings. Amended – Addition of critical subcontractors for manufacture. Amended – Addition of critical subcontractors for sterilization. Amended – Administrative update to the history.
2023-11-02	30028125	Supplemented – Addition of new device category to existing name Protective devices, lubricants and soothing devices (sprays, gels, fluids and creams) Amended – Addition of critical subcontractors for manufacture Amended – Addition of a critical subcontractor for gamma sterilisation

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Date	Reference number	Action
Current	30297684	Supplemented – Addition of new device category to existing name Protective devices, lubricants and soothing devices (sprays, gels, fluids and creams) Amended – Addition of critical subcontractor for manufacture

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