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 Medical Devices

First Issued: **2021-06-07** Date: **2022-03-18** Expiry Date: **2026-06-06**

...making excellence a habit.™

EU Quality Assurance Certificate

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

MDR 737173 R000

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

Device(s)	Risk Classification
Adhesive film dressings with or without absorbent pad	Class IIa
Skin closure strips	Class IIa
Silicone dressing	Class IIa
Low adherent absorbent dressings	Class Is
Non-woven dressings	Class Is
Catheter dressings	Class Is
Catheter fixation dressings	Class Is
Non-woven adhesive dressings	Class Is
Skin stapler handle	Class Is
Absorbent tracheostomy 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.	

First Issued: **2021-06-07** Date: **2022-03-18** Expiry Date: **2026-06-06**

...making excellence a habit.™

EU Quality Assurance Certificate

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

MDR 737173 R000

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 Allmed Medical Products Co., Ltd. as a subcontractor for Moist Heat Sterilization. Amended – Addition of Synergy Health Sterilisation UK Ltd as a subcontractor for ETO Sterilization. Amended – Addition of Sterigenics UK Ltd as a subcontractor for ETO Sterilization.
Current	3654158	Supplemented – Addition of device category silicone dressings.

First Issued: **2021-06-07** Date: **2022-03-18** Expiry Date: **2026-06-06**

...making excellence a habit.™