

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.

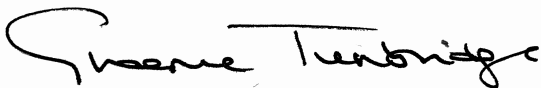
Address:

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**

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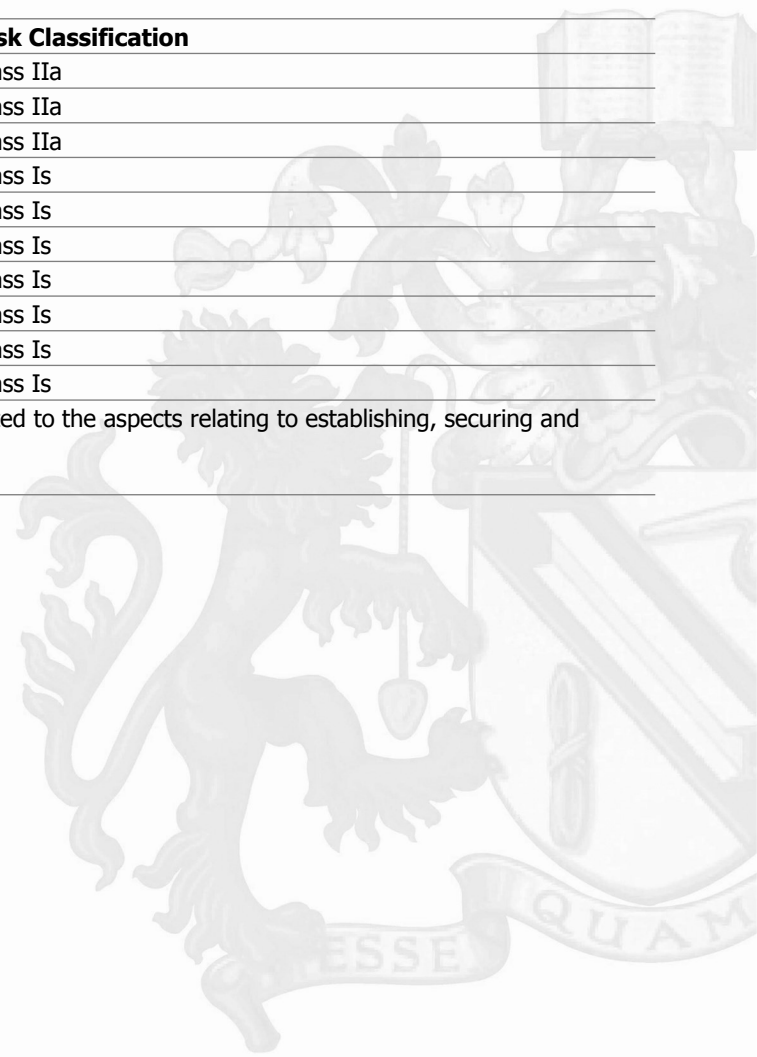
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Device Schedule: Class IIa, Custom-made and other devices

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.



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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 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.

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List of Critical Subcontractors and Crucial Suppliers

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

MDR 737173 R000

Date: 2022-03-18

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Allmed Medical Products Co., Ltd No.180 Gong Yuan Road Majiadian Town 443200 Zhijiang City Hubei Province People's Republic of China	Moist Heat Sterilization
Chemiczna Spoldzienia Pracy Technochemia ul. Fabryczna 3 05-600 Grojec Poland	ETO Sterilization
Shanghai ISO Medical Products Co., Ltd. 999 Liu Chen Rd Pudong New Area Shanghai P.R. China	Manufacture
Shanghai JPY ION-TECH Co., Ltd. No. 1168 Huijin Rd Shanghai Qingpu Industrial Zone 201707 Shanghai People's Republic of China	Radiation (Gamma Sterilization)
Smith & Nephew Medical (Suzhou) Limited No. 12, Wuxiang Road Comprehensive Free Zone, West Zone Suzhou Industrial Park Suzhou Jiangsu 215021 China	Manufacture

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Sterigenics Shanghai ETO Limited No. 333 Shuang Hui Road Yang Shan Free Port Shanghai 201308 China	ETO Sterilization
Sterigenics UK Ltd Cotes Park Lane Somercotes Alfreton DE55 4NJ United Kingdom	ETO Sterilization
SteriPack Medical Poland Sp. Z o. o. Łęg, ul. Japońska 1 55-220 Jelcz-Laskowice Poland	Manufacture
STERIS Sterilization Technologies (Suzhou) Ltd. 26 Xinchang Road Suzhou Industrial Park Jiangsu 215125 China	ETO Sterilization
Suzhou CNNC Huadong Radiation Co. Ltd. 4756 Jiaotong Road Economic and Technological Development Zone of Wujiang 215200 Suzhou Jiangsu Province China	Radiation (Gamma Sterilization)

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Date: 2022-03-18

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Synergy Health Sterilisation UK Ltd 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom	ETO Sterilization

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