By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 56481**

Issued To: **Smith & Nephew Medical Ltd**
101 Hessle Road
Hull
HU3 2BN
United Kingdom

In respect of:

The manufacture of sterile skin closure clips, non-sterile skin cleansers and protectants for use on compromised skin and non-sterile spray plasters.

Those aspects of Annex V related to securing and maintaining sterility of wound dressings, barrier films, skin preparations, adhesive gel patches, saline and skin closure clip accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

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

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2000-10-26** Date: **2020-02-27** Expiry Date: **2024-05-26**

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Supplementary Information to CE 56481

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Number	Device	Intended use per IFU
Class IIa		
MD 0302	Stapler cartridge	--
MD 0303	Skin cleansers	--
MD 0303	Skin protectants	--
MD 0301	Spray plasters	--
Class I sterile		
MD 0301	Non-woven dressing	--
MD 0301	Foam dressing	--
MD 0101	Catheter fixation dressing	--
MD 0301	Absorbent dressing	--
MD 0301	Tracheostomy dressing	--
MD 0301	Wound contact layer dressing	--
MD 0301	Barrier dressing	--
MD 0101	Film dressing	--
MD 0101	Diabetic infusion adhesive tape	--
MD 0301	Protective wipes	--
MD 0301	Barrier film	--
MD 0301	Barrier spray	--
MD 0302	Skin closure accessories	--
MD 0301	Adhesive gel patches	--

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Date	Reference Number	Action
26 October 2000		First issue.
11 July 2001		Scope extended to include skin closure products. Addition of sub-contractors.
21 March 2003		Addition of sub-contractor.
23 May 2003		Addition of sub-contractor.
01 July 2004		Addition of sub-contractor.
07 October 2004		Change of Artsana subcontractor address, change of subcontractor activities from sterilization to control of sterilization.
29 June 2005		5 year renewal.
09 February 2006		Change of subcontractor scope. Addition of HA2 Medizintechnik as a subcontractor for ETO Sterilization.
14 February 2007		Addition of China Surgical Dressings Center Co., Ltd as a subcontractor for Manufacture and Control of Sterilization. Addition of Allmed Medical Products Co., Ltd as a subcontractor for Manufacture, Control of Sterilization and Moist Heat Sterilization.
02 May 2007		Amendment of Company Name from 'Smith & Nephew Wound Management' to 'Smith & Nephew Medical Ltd'. Addition of Pharmaplast S.A.E. as a subcontractor for Manufacture, Control of Sterilization and ETO Sterilization.

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23 July 2007		Addition of Shanghai ISO Medical Products Co., Ltd as a subcontractor for Manufacture and Control of Sterilization. Amendment to subcontractors name from Toha Plast GmbH to Sartorius Toha Plast GmbH.
06 January 2010	7462300	Addition of new s/c S&N (Suzhou, China); update of trading name for s/c Sartorius Stedim Plastics GmbH; address update for s/c Allmed Medical.
24 November 2010	7474976	Renewal. Removal of 6 subcontractors: Flexible Medical Packaging Ltd; Beiersdorf AG; Pharmaplast S.A.E.; China Surgical Dressings; and HA2 Medizintechnik GmbH; Isotron Laboratories.
04 May 2011	7675127	Addition of new subcontractors: Sterigenics, Belgium (ETO sterilisation); and Artsana Spa, Casnate con Bernate, Italy (manufacture, design and control of sterilisation).
06 October 2015	8417971	Addition of significant subcontractors for manufacture and control of sterilisation of barrier films (Swiss American Products), sterile skin preparations (Span Packaging Services) and sterile gel patches (First Water Ltd).

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Date	Reference Number	Action
28 October 2015	8373931	Renewal. Removal of Sartorius Stedim Plastics, Artsana SpA, Sterigenics Holland BV and Chester Medical as significant subcontractor. Addition of control of sterilisation for Lantor (UK) Limited.
18 April 2016	8503299	Addition of subcontractor (SteriPack Medical Poland) for manufacture and control of sterilisation of Leukoclip. Addition of crucial suppliers.
26 July 2016	8560021	Extension to scope to include saline. Addition of Winchester Laboratories for manufacture and control of sterilisation. Change in company name for significant subcontractor Swiss American CDMO.
21 February 2019	9666437	Addition of Sub-contractor- Smith & Nephew Orthopaedics GmbH- authorised rep. Administrative corrections to address details for: Sterigenics Belgium, Sterigenics UK Limited and SteriPack Medical Poland Sp z.o.o

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Date	Reference Number	Action
27 February 2019	7779270	Traceable to NB 0086.
24 October 2019	9645314	Certificate renewal. Correction to service listed for sub-contractor Mediscan GmbH from crucial supplier to gamma sterilization. Correction to address for sub-contractor Sterigenics Belgium (Petit-Rechain) from Avenue du Parc 29, Verviers, B-4800, Belgium to Avenue Andre Ernst 21, Verviers, Liege, B-4800, Belgium. Correction to company name for sub-contractor STERIS Applied Sterilization Technologies Formerly Synergy Health Applied Sterilization Technologies from Synergy Health Sterilisation UK Ltd (Synergy Health – AST – Swindon). Correction to service listed for sub-contractor TECHNOCHEMIA from crucial supplier to ETO sterilization. Removal of manufacturing sub-contractor Winchester Laboratories. Minor corrections to addresses for Allmed Medical Products, Mediscan GmbH and Shanghai ISO Medical Products. Addition of supplementary information table.

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Date	Reference Number	Action
27 February 2020	3126174	Extension to scope to include class IIa non-sterile devices. Addition of manufacturing sub-contractor Colep Laupheim GmbH & Co. KG. Minor corrections to sub-contractors Lantor (UK) Limited trading as Nonwovenn, Smith & Nephew Medical (Suzhou) Limited, Sterigenics UK Ltd and Synergy Health Sterilisation UK Ltd (Synergy Health – AST – Daventry). Update to supplementary information table to include class II non-sterile devices.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
13 June 2023	30000501	Removal of a critical subcontractor for manufacture. Addition of a critical subcontractor for manufacture.

Inspiring trust for a more resilient world.

13 June 2023

Smith & Nephew Medical Ltd
101 Hessle Road
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 56481	93/42/EEC Annex V	30000501	Removal of critical subcontractor for manufacture. Addition of a critical subcontractor for manufacture.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices