By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 00356**

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

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 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: **1994-12-05** Date: **2020-01-31** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Certificate No: CE 00356

Certificate Scope:

The design and manufacture of sterile or non-sterile wound management products in the following categories: wound dressings (see supplementary page), medicated wound dressings, wound dressings utilising animal derived materials (porcine gelatin), medicated bandages, medicated bandages utilising animal derived materials (porcine gelatine), cavity wound dressings, wound preparations, wound monitoring devices, multi-layer bandage systems, Negative Pressure Wound Therapy Systems (NPWT), abdominal dressing kits for use with NPWT, drain kits and drain accessory kits for use with NPWT, and hydrosurgery systems for wound debridement.

Those aspects of Annex II relating to securing and maintaining sterilty in the assembly of procedure packs in accordance with Article 12 of the Medical Device Directive.

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Supplementary Information to CE 00356

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Number	Device Name	Intended Use per IFU
Class III		
MD 0301 MDS 7001 MDS 7006	Antimicrobial wound dressings	Refer to Design Examination certificates: CE 01105 CE 01409 CE 01714 CE 511078 CE 518880 CE 521887 CE 544419 CE 547893 CE 568730 CE 90692 CE 96076
MD 0301 MDS 7002 MDS 7006	Wound dressings containing porcine gelatine	Refer to Design Examination certificates: CE 01714 CE 650269

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Number	Device Name	Intended Use per IFU
Class IIb		
MD 0301	Foam wound dressings	Wound management by secondary intention on chronic and acute; full thickness, partial thickness or shallow; granulating, exuding wounds. Can also be used for pressure ulcer prevention
MD 0301	Hydrogel wound dressings	Management of shallow and deep open wounds healing by secondary intent
MD 0301	Odour absorbing non-woven wound dressings	For use on malodorous, partial to full thickness wounds and as a secondary dressing for superficial to full thickness wounds
MD 0303	Wound preparation devices	For the improvement/ management of the wound environment to promote healing in acute and chronic wounds
MD 0301	Superabsorbent wound dressings	For the treatment and management of exuding wounds

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Number	Device Name	Intended Use per IFU
MD 0301	Multi-layer bandage systems	For the management and treatment of venous leg ulcers and associated conditions
MD 0301	Alginate wound dressings	To treat pressure sores and venous leg ulcers, with moderate to heavy exudate. To facilitate the control of minor bleeding.
MD 0301	Gauze wound dressings	For the management of partial and full thickness wounds. For post-surgical covering over epithelial autograft sites and a means of stenting or anchoring skin substitutes. Can be used in conjunction with S&N Negative Pressure Wound Therapy (NPWT) systems
MD 1104	Hydrosurgery systems	Intended for wound debridement (acute, chronic wounds and burns), soft tissue debridement and cleansing of the surgical site

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Number	Device Name	Intended Use per IFU
MD 0301	Cellulose based wound dressings	Wound management by secondary intention on chronic and acute; full thickness, partial thickness or shallow; granulating, exuding wounds
MD 0301	Hydrocolloid wound dressings	For use in the management of dry or lightly exuding wounds to moderately exuding wounds
MD 1103	Single use negative pressure wound therapy (NPWT) systems and associated dressing kits	For patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudates and infectious materials
MD 1103	Traditional negative pressure wound therapy (NPWT) systems and associated dressing kits	For patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudates and infectious materials

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Number	Device Name	Intended Use per IFU
MD 0301	Abdominal dressing kits	Indicated for temporary bridging of abdominal wall openings where primary closure is not possible and / or repeat abdominal entries are necessary. It is intended to be used in open abdominal wounds with exposed viscera, including but not limited to abdominal compartment syndrome
MD 0303	Wound drainage kits	Intended to be used in conjunction with Smith & Nephew Negative Pressure Wound Therapy (NPWT) Systems

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Number	Device Name	Intended Use per IFU
Class IIa		
MD 0302	Skin closure devices	--
MD 0301	Film wound dressings	--
MD 0301	Tulle Gras wound dressings	--
MD 0301	Foam wound dressings	--
MD 0301	Hydrogel wound dressings	--

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Subcontractor:	**Service(s) supplied**
Avery Dennison België BVBA Tieblokkenlaan 1 2300 Turnhout Belgium	**Control of Sterilization** **Manufacture**
Azelis (Shanghai) Room 1002, Building 16 No.1000 Jin Hai Road Pudong 201206 Shanghai China	**Crucial Supplier**
Chester Medical Solutions Apex Court Bassendale Road Wirral Merseyside CH62 3RE United Kingdom	**Control of Sterilization** **Manufacture** **Packaging**

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Subcontractor:	**Service(s) supplied**
Derma Sciences, Inc. 104 Shorting Road Toronto Ontario M1S 3S4 Canada	**Control of Sterilization** **Manufacture**
Encube Ethicals Pvt. Ltd. C-1, Madkaim Industrial Estate Madkaim, Post Mardol Ponda Goa 403 404 India	**Manufacture**
EUROMED, Inc. 25 Corporate Drive Orangeburg New York, 10962 USA	**Control of Sterilization** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Flextronics Design S.r.l Via Ernesto Breda, 176 Milano 20126 Italy	**Design** **Software**
Flextronics Technology (Shenzhen) Co. Ltd. 3-6/F Building 1, 3B/F, 4/F Building 2, and 5-7/F Building 3, Rundongsheng Industrial Park, Longzhu, Xixiang, Baoan District, 518126 Shenzhen, Guangdong China	**Manufacture**
Gelita USA, Inc. 2445 Port Neal Industrial Road Sergeant Bluff IA 51054 USA	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
Harmac Medical Products IDA Buisness Park Castlerea Co. Rosommon Ireland	**Control of Sterilization** **Manufacture**
Isomedix Operations, Inc. 3459 South Clinton Avenue South Plainfield New Jersey 07080 USA	**ETO Sterilization**
Isomedix Operations, Inc. 2 Nucifora Boulevard Chester New York 10918 USA	**Radiation (E Beam Sterilization)**

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Subcontractor:	**Service(s) supplied**
Johnson Matthey plc 33 Jeffreys Road Brimsdown Enfield EN3 7PW United Kingdom	**Crucial Supplier**
Lantor (UK) Limited trading as Nonwovenn St Helens Road Bolton BL3 3PR United Kingdom	**Control of Sterilization** **Manufacture** **Moist Heat Sterilization**
Lohmann & Rauscher GmbH Kirchengasse 17 A-2525 Schönau a. d. Triesting Austria	**Control of Sterilization** **Manufacture**
Materion Corporation Advanced Materials Group Ballysimon Road Limerick, Ireland	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
Medichem S.A. Poligon Industrial de Celra 17460 Celra Girona Spain	**Crucial Supplier**
Mediplast Israel Ltd. 7 Hayarkon St., P.O. Box 13214 Industrial Zone, Yavne, 8122710 ISRAEL	**ETO Sterilization**
Mediscan GmbH & Co KG Im Forschungszentrum A-2444 Seibersdorf a.d. Leitha Austria	**Radiation (Gamma Sterilization)**

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Subcontractor:	**Service(s) supplied**
Midwest Sterilization Corporation P.O. Box 411 1204 Lenco Avenue Jackson Missouri 63755 USA	**ETO Sterilization**
NPA de Mexico S. de R.L. de C.V. Sor Juana Ines de la Cruz #20150, Interior 5 Cd. Industrial Tijuana Baja California CP 22444 Mexico	**Control of Sterilization** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Perstorp Specialty Chemicals AB, including Perstorp Pharma Perstorps Industripark Perstorp SE-284 80 Sweden	**Control of Sterilization** **Manufacture**
Plexus Corp. Livingston Design Centre Pyramids Business Park Easter Inch, Bathgate West Lothian EH48 2EH United Kingdom	**Software**
PLIVA Croatia Ltd Savski Marof Site Prudnicka Cesta 54 10291 Prigorje Brdovecko Croatia	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
Shanghai ISO Medical Products Co., Ltd 999 Liu Chen Road Pudong New Area 201202 Shanghai China	**Control of Sterilization** **Manufacture**
SHANGHAI JPY ION-TECH. CO., LTD. NO.1168, Huijin Rd Shanghai Qingpu Industrial Zone 201707 Shanghai China	**Radiation (Gamma Sterilization)**
Smith & Nephew Medical (Suzhou) Ltd No. 12, Wuxiang Road Comprehensive Free Zone, West Zone Suzhou Industrial Park 215021 Jiangsu Province China	**Control of Sterilization** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Smith & Nephew Orthopaedics GmbH Alemannenstraße 14 78532 Tuttlingen Germany	**EU Representative**
Smith & Nephew, Inc. Endoscopy Division 76 South Meridian Ave Oklahoma City Oklahoma 73107-6512 USA	**Control of Sterilization** **Manufacture**
Speciality Fibres and Materials Ltd 101 Lockhurst Lane Coventry CV6 5RS United Kingdom	**Control of Sterilization** **Crucial Supplier** **Design** **Manufacture**

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Subcontractor:	**Service(s) supplied**
SQM-SA (Sociedad Quimica y Minera de Chile S.A.) Oficina Santiago El Trovador 4285, Poiso 4 Las Condes Santiago Chile	**Crucial Supplier**
SQM-SA (Sociedad Quimica y Minera de Chile S.A.) Planta Nueva Victoria Ruta 5 Norte Km 1725 Pozo Almonte I Region Chile	**Crucial Supplier**
SQM-SA (Sociedad Quimica y Minera de Chile S.A.) Planta Pedro Valdivia SQM Maria Elena, II Region Chile	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
Sterigenics Belgium (Petit-Rechain) SA Zoning Industriel de Petit Rechain Avenue Andre Ernst 21 Verviers B-4800 Belgium	**ETO Sterilization**
Sterigenics Holland BV Storkstraat 8-10 2722 NN Zoetermeer The Netherlands	**ETO Sterilization**
Sterigenics Shanghai ETO Ltd. No. 333, Shuang Hui Road, Yang Shan Free Port, Shanghai, 201 308 China	**ETO Sterilization**

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Sterigenics UK Ltd Cotes Park Lane Somercotes Alfreton DE55 4NJ United Kingdom	**ETO Sterilization**
Sterigenics US, LLC 4900 Gifford Ave Los Angeles California 90058 USA	**ETO Sterilization**
Sterigenics US, LLC 1003 Lakeside Drive Gurnee Illinois 60031 USA	**Radiation (Gamma Sterilization)**

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Subcontractor:	**Service(s) supplied**
STERIS AST CZ s.r.o. Prumyslová Zona Kosikov 80 Velka Bites 59501 Czech Republic	**ETO Sterilization**
STERIS Sterilization Technologies (Suzhou) Ltd No. 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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Subcontractor:	**Service(s) supplied**
Synergy Health AST, LLC 7225 North Noah Drive Saxonburg Pennsylvania 16056 USA	**Radiation (E Beam Sterilization)**
Synergy Health Ireland Ltd. (Synergy Health – AST – Ireland) IDA Business & Technology Park Tullamore Co. Offaly Ireland	**ETO Sterilization**
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Daventry) Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	**Radiation (E Beam Sterilization)** **Radiation (Gamma Sterilization)**

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Subcontractor:	**Service(s) supplied**
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Thorne) 1 Alpha Court Capitol Park Thorne Doncaster DN8 5TZ United Kingdom	**ETO Sterilization**
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Reading) Marcus Close Tilehurst Reading Berkshire RG30 4EA United Kingdom	**Radiation (Gamma Sterilization)**

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Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00356**
Date:	**2020-01-31**
Issued To:	**Smith & Nephew Medical Ltd** **101 Hessle Road** **Hull** **HU3 2BN** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Bradford) Roydsadale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	**Radiation (Gamma Sterilization)**
Teva API B.V. Piet Hein Building Piet Heinkade 107 1019 GM Amsterdam The Netherlands	**Crucial Supplier**
Viant Medical Inc. 5079 33rd Street SE Grand Rapids Michigan 49512 USA	**Control of Sterilization** **Manufacture**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00356**
Date:	**2020-01-31**
Issued To:	**Smith & Nephew Medical Ltd** **101 Hessle Road** **Hull** **HU3 2BN** **United Kingdom**

Subcontractor:	**Service(s) supplied**
Winner Medical (Chongyang) Co., Ltd. No. 9A, Jincheng Avenue, Zhongjin Village, Tiancheng Town, 437500 Chongyang, Hubei, People's Republic of China	**Control of Sterilization** **Manufacture**
Zhongjin Irradiation WuHan Co., Ltd. No. 55 Jinyang Rd. Yangluo Economic Development Zone 430415 Wuhan Hubei Province People's Republic of China	**Radiation (Gamma Sterilization)**

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By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 00356**

Date: **2020-01-31**

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

Date	Reference Number	Action
07 October 2004		Change of subcontractors activities from sterilization to control of sterilization.
24 June 2005		Change to scope, addition of supplementary information and addition of Nucryst Pharmaceuticals Corp. (Alberta), Steris Corporation Ismedix Services (Ontario) and Iotron Technologies Corp. (British Columbia) as subcontractors. Change of subcontractor name from "Smith & Nephew Fabrics" to "BSN Medical".
4 August 2005		Addition of 'Beam One LLC' as a subcontractor for E beam sterilization.
10 January 2006		Addition of Codan Steritex ApS as a subcontractor for Gamma Sterilization. Spelling correction to "Speciality" to read "Specialty" for Perstorp Specialty Chemicals AB.
30 January 2006		Addition of NAmSA (North American Science Associates, Inc) as a subcontractor for Microbiology Service.
16 March 2006		Addition of Derma Sciences, Inc as a subcontractor for Manufacture of Gauze dressings. Addition of Coloplast Corp as a subcontractor for Manufacture of Hydrocolloid dressings.

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

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Date	Reference Number	Action
26 April 2006		Addition to subcontractor activities for Derma Sciences, Inc and Coloplast Corp.
11 August 2006		Addition of Isotron plc (Reading) as a subcontractor for Gamma Sterilization.
07 December 2006		5 year certificate renewal and addition of Iotron Industries Canada, Inc. as a subcontractor for E Beam Sterilization.
01 March 2007		Amendment of Company Name from 'Smith & Nephew Wound Management' to 'Smith & Nephew Medical Ltd'. Removal of Beiersdorf AG from the list of significant subcontractors.
02 May 2007		Change of name of subcontractor Acordis Speciality Fibres to Speciality Fibres and Materials Ltd. Addition of Pharmaplast S.A.E. as a subcontractor for Manufacture, Control of Sterilization and ETO Sterilization.
24 October 2007		Addition of BeamOne LLC (both Denver and Lima sites) as significant subcontractors for E Beam Sterilisation.
06 July 2009	7392715	Addition of Smith & Nephew Medical (Suzhou) Limited as a subcontractor.

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Date	Reference Number	Action
29 April 2010	7506261	Extension to scope to include cellulose based gelling dressings. Subcontractor name change: Nucryst Pharmaceuticals Corp updated to Smith & Nephew (Alberta) Inc.
4 May 2011	7675089	Scope extension to include Negative Pressure Wound Therapy Systems. Addition of new subcontractors Avail Medical Products Inc., Texas, FLEXMedical Dallas, Texas and Sterigenics, Belgium.
13 July 2011	7715729	Addition of new subcontractor: Flextronics Technology (Shenzhen) Co. Ltd. for the activity of manufacture.
14 October 2011	7760098	Addition of new subcontractor KARL OTTO BRAUN GmbH & Co. KG, Germany for the activity of manufacture.
13 December 2011	7571924	Certificate renewal and removal of unused subcontractors. Beam One LLC, Denver, Advanced Medical Solutions, Winsford, Riverside Medical Packaging, Derby, BSN Medical, Lancs, Beam One LLC, San Diego, Codan Steritex, Denmark, NAmSA, Ohio, Pharmaplast, Egypt, Iotron Industries Canada, Steris Corporation, Ontario, Beam One, Ohio, Smith & Nephew Inc., Florida and Coloplast Corp., MN.

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Date	Reference Number	Action
18 February 2013	7858491	Update to trading name for Synergy Health subcontractor locations (formerly Isotron); removal of subcontractor Isotron Laboratories, Swindon; addition of subcontractor Chemviron Carbon Ltd; addition of subcontractor Biodaptive LLC.
19 December 2014	8225325	Addition of crucial suppliers Johnson Matthey plc, Azelis Life Sciences Ltd, SQM-SA Chile (3 sites), Medichem S.A., Azelis (Shanghai), PLIVA Croatia Ltd and Teva API B.V. Addition of significant subcontractor Shanghai ISO Medical Products Co., Ltd.
20 October 2015	8333800 8333612 8418001	Extension to scope to include hydrosurgery systems for wound debridement. Addition of significant subcontractors for manufacture (NPA De México S. de R.L. de C.V.; Smith & Nephew Inc) and ETO sterilisation (Sterigenics US LLC) for Versajet. Addition of significant subcontractors for manufacture and control of sterilisation for hydrocolloid dressings (Euromed Inc); gel and gauze dressings (Winner Industries) and NPWT systems and associated foam dressing kits (Smith & Nephew Inc Endoscopy, Vention Medical, Harmac Medical Products).

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Date	Reference Number	Action
09 December 2015	8440432	Removal of significant subcontractor, Smith & Nephew (Alberta).
02 March 2016	8480952	Extension to scope to include abdominal dressing kits for use with NPWT. Addition of significant subcontractor for software development of Renasys (Plexus).
17 June 2016	8487212	Addition of significant subcontractor, Steripack, Malaysia for manufacture and control of sterilisation of Biobrane; extension to scope to include wound dressings utilising animal derived materials (porcine gelatin).
26 July 2016	8544325 8514831	Addition of Smith & Nephew, Inc as significant subcontractor for manufacture and control of sterilisation of RENASYS soft port foam dressing kits. Extension to scope to include drain kits and accessory kits for use with Negative Pressure Wound Therapy.

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Date	Reference Number	Action
30 November 2016	8632203	Certificate Renewal. Addition of significant subcontractors Flextronics Design S.r.l and Flextronics International Inc for software and design of PICO. Removal of significant subcontractors Chemviron, Biodaptive, Avail Medical Products, Hardwood Products, Karl Otto Braun and Flexmedical Dallas.
	8429534	Gelita listed as crucial supplier. Extension to scope to include superabsorbers. Addition of Lohmann & Rauscher for manufacture and control of sterilisation of Duramax.
16 February 2017	8676637	Addition of gamma sterilisation services for Synergy Health Sterilisation, Daventry.
03 May 2017	8712342	Addition of Gelita USA as a crucial supplier.
16 June 2017	8647800	Addition of Aspen Medical Europe Limited as a significant subcontractor. Addition of Aspen Surgical Products and Specialist Fibres and Materials Limited as a crucial supplier.

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Date	Reference Number	Action
21 July 2017	8762343	Addition of Aspen Surgical Products as a Finished Device Supplier. Removal of Aspen Europe Limited as a Finished Device Supplier. Addition of Sterigenics US LLC (Gurnee) for gamma sterilisation.
04 January 2018	8857448	Addition of significant subcontractors Plexus (manufacture) and PA Consulting (design and software).
03 April 2018	8887161	Addition of significant subcontractors Midwest Sterilisation Corporation as ETO Sterilization, and Encube Ethicals Pvt. Ltd. For Manufacture. Amendment to scope to include 'Those aspects of Annex II relating to securing and maintaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Device Directive.'
20 November 2018	8902999	Addition of Suzhou CNNC Huadong for sterilisation of Bactigras. Removal of significant subcontractors Azelis Life Science Ltd, Gelita Sweden AB and Smith & Nephew Inc.
23 February 2019	9666435	Addition of authorised representative Smith & Nephew Orthopaedics GmbH. Administrative corrections to address details for, Speciality Fibres and Materials Ltd, Sterigenics UK Limited and Synergy Health Sterilisation.
27 February 2019	7779270	Traceable to NB 0086.

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Date	Reference Number	Action
31 January 2020	3054769	Certificate renewal Addition of sub-contractors; Isomedix Operations Inc, Shanghai JPY ION-TECH, Synergy Health (Suzhou), Sterigenics Shanghai ETO, Synergy Health AST LLC, Synergy Health Ireland and Plexus Corp. UK. Removal of sub-contractors; Flextronics International, Plexus Corp. USA, PA Consulting Services and Plexus Manufacturing SDN BHD. Sub-contractor name change from Vention Medical, Inc. to Viant Medical, Inc. Administrative updates to correct address information for the following sub-contractors; Avery Dennison, Chester Medical Solutions, Derma Sciences, Flextronics (Shanghai), Lantor (UK) Limited, Lohman & Rauscher, NPA de Mexico S. de R.L. de C.V., Perstorp Specialty Chemicals, Smith & Nephew Medical (Suzhou) Limited, Sterigenics UK Limited, Suzhou CNNC, Synergy Health Sterilisation UK Ltd in Daventry, Synergy Health Sterilisation UK Ltd in Reading and Winner Medical Co., Ltd. Inclusion of product supplementary information table Removal of TIO NPWT system from scope of certification due to discontinuation of product.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		

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Date	Reference Number	Action
30 November 2021	3513597	Removal of references to CE 650269, CE 01409 and CE 521887 from supplementary information table, following cancellation of these certificates. Update to address for Flextronics Technology (Shenzhen) Co. Ltd. Addition of Sterigenics US, LLC (California), Mediplast Israel Ltd. and STERIS AST CZ s.r.o. (Velka Bites) as subcontractors for ETO Sterilization. Addition of Materion Corporation as a Crucial Supplier. Addition of Zhongjin Irradiation WuHan Co., Ltd. as a subcontractor for Radiation (Gamma Sterilization). Addition of Isomedix Operations, Inc. (2 Nucifora Boulevard, Chester) as a subcontractor for E Beam Sterilization. Addition of Winner Medical (Chongyang) Co., Ltd. as a subcontractor for Control of Sterilization and Manufacture. Change of subcontractor name from Synergy Health (Suzhou) Sterilization Technologies Ltd to STERIS Sterilization Technologies (Suzhou) Ltd. Removal of Aspen Surgical Products, Inc. as a Finished Device Supplier. Removal of SteriPack Asia (M) Sdn Bhd (Selangor) as a subcontractor for Control of Sterilization and Manufacture. Removal of Winner Medical Co., Ltd. as a subcontractor for Control of Sterilization and Manufacture.

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Inspiring trust for a more resilient world.

30 November 2021

Smith & Nephew Medical Ltd
101 Hessle Road
Hull
HU3 2BN
United Kingdom

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 00356	93/42/EEC Annex II excluding Section 4	3513597	Removal of references to CE 650269, CE 01409 and CE 521887 from supplementary information table, following cancellation of these certificates. Update to address for Flextronics Technology (Shenzhen) Co. Ltd. Addition of Sterigenics US, LLC (California), Mediplast Israel Ltd. and STERIS AST CZ s.r.o. (Velka Bites) as subcontractors for ETO Sterilization. Addition of Materion Corporation as a Crucial Supplier. Addition of Zhongjin Irradiation WuHan Co., Ltd. as a subcontractor for Radiation (Gamma Sterilization). Addition of Isomedix Operations, Inc. (2 Nucifora Boulevard, Chester) as a subcontractor for E Beam Sterilization. Addition of Winner Medical (Chongyang) Co., Ltd. as a subcontractor for Control of Sterilization and Manufacture. Change of subcontractor name from Synergy Health (Suzhou) Sterilization Technologies Ltd to STERIS Sterilization Technologies (Suzhou) Ltd. Removal of Aspen Surgical Products, Inc. as a Finished Device Supplier. Removal of SteriPack Asia (M) Sdn Bhd (Selangor) as a subcontractor for Control of Sterilization and Manufacture. Removal of Winner Medical Co., Ltd. as a subcontractor for Control of Sterilization and Manufacture.

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SUSTAINABLE DEVELOPMENT GOALS

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,



Gary Slack
Senior Vice President, Medical Devices

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