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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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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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BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 00356

Issued To:

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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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