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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