By Royal Charter

EC Design-Examination Certificate

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

No. **CE 547893**

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

In respect of:

Acticoat Flex 3
Silver-Coated Antimicrobial Wound Dressings

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **2009-08-28** Date: **2019-08-28** Expiry Date: **2024-05-26**

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Supplementary Information to CE 547893

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Product Code	Size	Device Name	Intended Purpose per IFU	Classification
66800396	5cm x 5cm	Acticoat Flex 3	ACTICOAT Flex 3 is indicated as an antimicrobial barrier dressing over partial and full thickness wounds such as burns, recipient graft sites, surgical sites, pressure ulcers, venous ulcers and diabetic ulcers. ACTICOAT Flex 3 may be used on infected wounds. Where the product is used on infected wounds the infection should be inspected and treated as per local clinical protocol. ACTICOAT Flex 3 may be used as a wound contact layer in combination with Negative Pressure Wound Therapy (NPWT) for a period of up to 3 days.	III
66800398	10cm x 10cm			
66800399	10cm x 10cm			
66800409	10cm x 20cm			
66800419	20cm x 40cm			
66800432	40cm x 40cm			
66800435	10cm x 120cm			
66801290	4cm x 15cm			
66801291	4cm x 25cm			
66801292	4cm x 35cm			
66801293	20cm x 2cm			

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Certificate History

Date	Reference Number	Action
28 August 2009	10103407	First issue. MHRA Consultation Reference NB14607 / 0099.
06 October 2010	10117657	Relocation of manufacturing operations from Smith & Nephew, Alberta to Smith & Nephew, Hull.
17 August 2011	10123324	Shelf life extension from 24 months to 34 months.
28 February 2013	10139715	Addition of new sizes to the product range and update to certificate format.
12 July 2014	10146220	Certificate renewal.
15 October 2014	10151666	Extension of shelf-life to 24 weeks for intermediate silver coated substrate.
18 August 2015	10156749	Transfer of silver coating and slitting processes to Smith & Nephew Medical Hull.
15 January 2016	10159973	DuPont Tyvek packaging change.
16 February 2017	10167667	Change of sterilisation site to Synergy Health, Daventry.
27 February 2019	7779270	Traceable to NB 0086.
Current	9756639	Renewal. Addition of EU Representative details to product labelling.

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