By Royal Charter

EC Design-Examination Certificate

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

No. **CE 90692**

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

In respect of:

Acticoat/Argencoat/Acticoat 7
Silver-Coated Antimicrobial Barrier 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: **2005-06-24** Date: **2020-06-03** Expiry Date: **2024-05-26**

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Supplementary Information to CE 90692

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Catalogue number	Device name	Model, Type	Intended purpose per IFU	Classification
66000808	Acticoat	5x5cm, carton of 5	For use over partial and full thickness wounds such as pressure ulcers, venous ulcers, diabetic ulcers, burns, recipient graft sites, and intravenous catheter insertion sites (5cm x 5cm only). May be used as a wound contact layer in combination with Negative Pressure Wound Therapy (NPWT) for a period of up to 3 days. 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.	Class III
66000789	Acticoat	10x10cm, carton of 5		
66000791	Acticoat	10x10cm, carton of 12		
66000792	Acticoat	10x20cm, carton of 12		
66000793	Acticoat	20x40cm, carton of 6		
66000794	Acticoat	40x40cm, carton of 6		
66000795	Acticoat	10x120cm, carton of 6		

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Catalogue number	Device name	Model, Type	Intended purpose per IFU	Classification
66350842	Argencoat	15x15cm, carton of 3	Indicated to treat venous leg ulcers and pressure ulcers where bacterial contamination or infection exists or when there is high risk of infection. When the product is used on infected wounds the infection should be inspected and treated as per local clinical protocol.	Class III

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Catalogue number	Device name	Model, Type	Intended purpose per IFU	Classification
66000809	Acticoat 7	5x5cm, carton of 5	For use over partial and full thickness wound such as pressure ulcers, venous ulcers, diabetic ulcers, burns, and recipient graft sites. 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.	Class III
66000796	Acticoat 7	10x12.5cm, carton of 5		
66000797	Acticoat 7	15x15cm, carton of 5		

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Date	Reference Number	Action
24 June 2005	10062965	First issue. Transfer from TUV Certificate G7 03 01 24028 003.
7 March 2006	10073252	Additional intended use for product code 66000808 (5cm x 5cm).
01 March 2007	10083706	Changes to the package labelling and IFU for Argencoat (Acticoat for Spain).
26 October 2009	10108977	Extension of shelf life to 39 months.
11 August 2010	10116213	Certificate renewal.
08 October 2010	10117654	Relocation of manufacturing operations from Smith & Nephew, Alberta to Smith & Nephew, Hull.
24 June 2011	101100441	Updated indications to include Negative Pressure Wound Therapy.
15 October 2014	10151666	Administrative update to certificate format. Extension of shelf-life to 24 weeks for intermediate silver coated substrate.
19 June 2015	10156212	Certificate renewal.

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Date	Reference Number	Action
28 September 2015	10156751	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	3007820	Certificate renewal. Addition of EU Rep to product labelling. Update to supplementary information table to current format.

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