By Royal Charter

EC Design-Examination Certificate

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

No. **CE 511078**

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

In respect of:

IODOSORB Woundcare Devices Containing Iodine

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: **2007-01-19** Date: **2021-04-05** Expiry Date: **2024-05-26**

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IODOSORB Powder (also sold as IODOSORB Mikro-Pellets):

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
66001286	IODOSORB Powder	7 x 3g Sachet	IODOSORB is indicated for the topical treatment of chronic exuding wounds. IODOSORB can be used under compression therapy. IODOSORB 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

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IODOSORB Ointment (also sold as IODOSORB Salbe):

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
66001298	IODOSORB Tube	4 x 10g Tube	IODOSORB is indicated for the topical treatment of chronic exuding wounds. IODOSORB can be used under compression therapy. IODOSORB 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
66001297	IODOSORB Tube	2 x 20g Tube		Class III
66001295	IODOSORB Tube	2 x 20g Tube		Class III
66001296	IODOSORB Tube	1 x 40g Tube		Class III
66001299	IODOSORB Tube	1 x 40g Tube		Class III

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IODOSORB Dressing (also sold as Iodoflex):

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
66001290	IODOSORB Dressing	5 x 5g Sachet	IODOSORB is indicated for the topical treatment of chronic exuding wounds. IODOSORB can be used under compression therapy. IODOSORB 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
66001301	IODOSORB Dressing	5 x 5g Sachet		Class III
66001291	IODOSORB Dressing	3 x 10g Sachet		Class III
66001292	IODOSORB Dressing	5 x 10g Sachet		Class III
66001302	IODOSORB Dressing	3 x 10g Sachet		Class III
66001293	IODOSORB Dressing	2 x 17g Sachet		Class III
66001303	IODOSORB Dressing	2 x 17g Sachet		Class III

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Certificate History

Date	Reference Number	Action
19 January 2007	10081353	First Issue. MHRA Consultation Number NB 14607 / 0079.
14 July 2011	10125093	Change of iodine supplier and source.
08 March 2012	10132412	Certificate Renewal.
18 February 2016	10161247	Addition of a new sterilisation site (Mediscan, Linz Austria).
22 December 2016	10166395 10164658	Change of manufacturing site of primary packaging for IODOSORB Ointment. Change to thickness of the aluminium layer of primary packaging for IODOSORB dressing and IODOSORB powder. Certificate Renewal.

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Date	Reference Number	Action

21 February 2019	9644652	10g tube IODOSORB (66001298)
		• Packaging configuration change
		  ○ Change from carton of 4 x 10g tubes to 1 x 10g tube per carton
		  ○ 4 cartons shrink wrapped together
		• Labelling change
		  ○ Addition of 2D NHS UDI compliant bar code
		  ○ Carton quantity amended
		  ○ Additional symbols added 'consult instructions for use' and 'store away from sunlight'
		  ○ Additional label applied to the shrink wrapped sales unit of 4 tubes.

27 February 2019	7779270	Traceable to NB 0086.

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Date	Reference Number	Action
25 September 2020	3279116	Removal of product codes 66001284, 66001285 and 66001288. Administrative update to supplementary information tables. 20g tube IODOSORB (66001297 & 66001295): • Packaging configuration change ○ Change from carton of 2 x 20g tubes to 1 x 20g tube per carton ○ 2 cartons shrink wrapped together • Labelling changes ○ Addition of 2D NHS UDI compliant bar code ○ Carton quantity amended ○ Additional symbols added 'consult instructions for use', keep away from sunlight', 'keep dry', 'storage temperature limits', and 'do not use if packaging is damaged' ○ Replace # with REF ○ Remove EXP text from 'hourglass' symbol ○ Update Notified Body Number from 0086 to 2797

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Date	Reference Number	Action
25 September 2020	3279116	Additional symbols added to IFU for: 'legal manufacturer', 'do not use if packaging is damaged', 'do not re-use', 'consult IFU', 'caution', 'keep dry', 'upper limit of temperature', 'keep away from sunlight' and notified body number updated from 0086 to 2797. Additional label applied to the shrink wrapped sales unit of 2 tubes.
21 December 2020	3326206	Addition of EU Rep details to product labelling and IFU. Voluntary scope reduction; removal of product code 66001287 (IODOSORB Powder 1x 25g bottle). Update to supplementary information table to remove product code 66001287.
Current	3385873	Certificate renewal.

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