

## EUROPEAN DECLARATION OF CONFORMITY

This Declaration confirms that the product listed below meets the Essential Requirements set out in Annex I of the Council Directive 93/42/EEC of 14<sup>th</sup> June 1993 (as amended) concerning medical devices.

<b>Manufacturer's Name:</b>	Smith and Nephew Medical Limited
<b>Business Address:</b>	101 Hessle Road, Hull HU3 2BN United Kingdom
<b>Authorised Representative:</b>	Smith & Nephew Orthopaedics GmbH, Alemannenstraße 14, 78532 Tuttlingen, Germany
<b>Medical Devices:</b>	IODOSORB Dressing IODOSORB Powder IODOSORB Ointment
<b>Classification :</b>	Class III Sterile
<b>GMDN Code and Term:</b>	47474 Exudate-absorbent dressing, hydrophilic-gel, antimicrobial, sterile
<b>Scope of Application:</b>	All batches supplied to which the Declaration of Conformity Procedure has been applied.
<b>Declaration :</b>	Conformity of the product has been assessed in accordance with Annex II of the Directive including design examination. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier of Technical Documentation.
<b>Verification Certificate(s):</b>	EC Certificate No. CE 00356 Full Quality Assurance (British Standards Institute) Notified Body No. 2797 .Certificate No. MD 76718 Quality Management System (BS EN ISO 13485) British Standards Institute. Certificate No. FM 24676 Quality Management System (BS EN ISO 9001). EC Design Examination Certificate CE 511078

**Standards Applied:**

- BS EN ISO 9001:2015
- BS EN ISO 13485:2016
- BS EN ISO 14971:2012
- BS EN 556-1:2001/AC:2006
- BS EN ISO 11137-1:2015
- BS EN ISO 11137-2:2015
- BS EN ISO 14644-1:2015
- BS EN ISO 11607-1:2009+A1:2014
- BS EN ISO 11607-2:2006+A1:2014
- BS EN ISO 780:2015
- BS EN 1041:2008
- BS EN ISO 10993-1:2018
- BS EN ISO 10993-3:2014
- BS EN ISO 10993-5:2009
- BS EN ISO 10993-10:2013
- BS EN ISO 10993-11:2018
- BS EN ISO 10993-17:2009
- BS EN ISO 10993-18:2009
- BS EN ISO 15223-1:2016

Product Family	Product Code	Product Description
Iodosorb Dressing	66001301	5x5g IODOFLEX Cadexomer Dressing with Iodine
	66001302	3x10g IODOFLEX Cadexomer Dressing with Iodine
	66001303	2x17g IODOFLEX Cadexomer Dressing with Iodine
	66001290	5x5g IODOSORB DRESSING
	66001292	5x10g IODOSORB DRESSING
	66001291	3x10g IODOSORB DRESSING

	66001293	2x17g IODOSORB DRESSING
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Product Family	Product Code	Product Description
Iodosorb Ointment	66001298	4x10g IODOSORB OINTMENT
	66001295	2x20g IODOSORB SALBE
	66001296	1x40g IODOSORB SALBE
	66001297	2x20g IODOSORB OINTMENT
	66001299	1x40g IODOSORB OINTMENT

Product Family	Product Code	Product Description
Iodosorb Powder	66001286	7x3g IODOSORB POWDER

**Name :**

Ken Fergusson

**Position :**

Senior Regulatory Affairs Manager

**Signed :**

  
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**Dated :**

13 OCT 2021

**Certificate Reference :**

DC 009 Issue 010