

Wound Management
Smith & Nephew
Medical Ltd.
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Hull HU3 2BN
England

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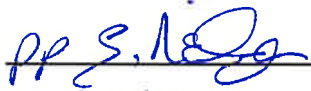
 We are **smith&nephew**

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 (as amended).

Manufacturer's Name: Smith & Nephew Medical Limited
Business Address: 101 Hessle Road,
Hull
HU3 2BN
United Kingdom
Medical Devices: ACTICOAT Flex 3
Classification: Class III
GMDN Code and Term: 47042, Wound no-adherent dressing, absorbent, antimicrobial
Scope of Application: All batches supplied to which the Declaration of Conformity Procedure has been applied.
Declaration: Conformity of the product has been assessed in accordance with Annex II of the Directive. A dossier of technical documentation, as required by the Directive is available. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier.
Verification Certificate(s): EC Certificate No. CE 00356 Full Quality Assurance.
Notified Body No. 0086 (British Standards Institute)
British Standards Institute. 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)
Design Examination Certificate: CE 547893
Standards Applied:

BS EN ISO 13485: 2012	BS EN ISO 9001: 2008
BS EN ISO 14971: 2012	BS EN 1041: 2008
BS EN ISO 15223-1:2012	BS EN ISO 780:1999
BS EN 980: 2008	BS EN ISO 11607-1: 2009
BS EN 13726-1:2002/AC:2003	BS EN 13726-2: 2002
BS EN 13726-3: 2003	BS EN 13726-4:2003
BS EN ISO 10993-1:October 2009/AC:2010	
BS EN ISO 10993-2:2006	BS EN ISO 10993:3-2014
BS EN ISO 10993-5:2009	BS EN ISO 10993-10:2013
BS EN ISO 10993-18: 2009	BS EN ISO 11137:1-2006
BS EN 556-1:2001/AC:2006	BS EN ISO 11137-2:2015
BS EN ISO 14644 -1:1999/AC: 2001	

Authorised Signatory:
Name: Susan McLoughlin
Position: Director, Regulatory Affairs
Signed: 
Dated: 10/12/2015
Certificate Reference DC012 issue 010