

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 14th June 1993 (as amended).

Manufacturer's Name : Smith and Nephew Medical Limited

Business Address : 101 Hessle Road,
Hull
HU3 2BN
United Kingdom

Medical Devices : ALLEVYN Ag Heel

Classification : Class III

GMDN Code and Term : 47042 Wound-non 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 CE 518880

Certificate :

Standards Applied :

BS EN ISO 13485: 2012	BS EN ISO 14971: 2012
BS EN ISO 9001: 2008	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 15223-1:2012
BS EN ISO 780:1999	BS EN 1041: 2008
BS EN ISO 10993-1:2009/ AC:2010	BS EN ISO 10993-2:2006
BS EN ISO 10993-3:2003	BS EN ISO 10993-5:2009
BS EN ISO 10993-10:2010	BS EN ISO 10993-18: 2009
BS EN 556-1:2001/AC:2006	BS EN ISO 11137-1:2006
BS EN ISO 11607-1: 2009	
BS EN ISO 11137-2:2007/AC:2009	
BS EN ISO 14644 -1:1999/AC: 2001	

Authorised Signatory :

Name :

Position :

Signed :

Jane Hare
SVP Healthcare Systems



Dated :

Certificate Reference :

5th June, 2013
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