

Wound Management
Smith & Nephew
Medical Ltd
101 Hessle Road
Hull HU3 2BN
England

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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 and Nephew Medical Limited
Business Address : 101 Hessle Road,
Hull
HU3 2BN
United Kingdom
Medical Devices : ALLEVYN Non-Adhesive
ALLEVYN Heel
ALLEVYN Schaumverband Ferse Nicht Haftend
ALLEVYN Schaumverband Nicht Haftend
Classification : Class IIb Sterile
GMDN Code and Term : 44970 - Highly absorbent dressing, non-hydrophilic-gel-forming
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)
Standards Applied : BS EN ISO 13485: 2012 BS EN ISO 9001: 2008
BS EN ISO 14971: 2012 BS EN ISO 11137:1-2006
BS EN ISO 11607-1: 2009 BS EN ISO 11137-2:2012
BS EN 13726-3: 2003 BS EN 13726-4:2003
BS EN ISO 780:1999 BS EN 1041: 2008
BS EN ISO 10993:3-2009 BS EN ISO 10993-5:2009
BS EN ISO 10993-10:201 BS EN ISO 10993-18: 2009
BS EN ISO 10993-2:2006 BS EN 556-1:2001/AC:2006
BS EN 13726-2: 2002 BS EN 13726-1:2002/AC:2003
BS EN ISO 15223:2012 BS EN ISO 10993-1:2009/ AC:2010
BS EN ISO 14644 -1:1999/AC: 2001
BS EN ISO 11737 -1:2006/AC:2009
Authorised Signatory :
Name : pp Jane Hare
Position : SVP Healthcare Systems
Signed : Helen M. May
Dated : 20th February 2014
Certificate Reference: HU/008 issue 029