

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

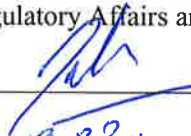
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EUROPEAN DECLARATION OF CONFORMITY

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 : JELONET/JELONET Lite
Classification : Class IIa Sterile
GMDN Code and Term : 46855 Wound-non adherent dressing, permeable
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 9001:2008 BS EN ISO 13485: 2012
BS EN ISO 14971:2012 BS EN 556-1:2001/AC:2006
BS EN ISO 11137-2:2007/ AC:2009
BS EN ISO 11737 -1:2006/AC:2009
BS EN ISO 14644-1:1999 BS EN 1041: 2008
BS EN ISO 15223-1:2012 BS EN ISO 780:1999
BS EN ISO 10993-1:2009 / AC:2010
BS EN ISO 10993-2:2006 BS EN ISO 10993-3:2009
BS EN ISO 10993-5:2009
BS EN ISO 10993-7:2008/AC:2009
BS EN ISO 10993-10:2013 BS EN ISO 10993-12:2012
BS EN ISO 10993-18:2009 BS EN ISO 11607-1:2009
BS EN ISO 11607-2:2006 EN 980:2008

Authorised Signatory :
Name : Richard Wilkins
Position : VP Regulatory Affairs and Quality
Signed : 
Dated : 19.12.2014
Certificate Reference HU/035 issue 015