

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

T 44 (0) 1482 225 181
F 44 (0) 1482 328 326
www.smith-nephew.com




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 : OPSITE Flexigrid
Classification : Class IIa
GMDN Code and Term : 17428 – Semi-permeable film dressing.
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 13485:2003 BS EN 980:2008
BS EN 556 -1:2001/AC:2006 BS EN 14971: 2007
BS EN ISO 10993 *Part 1:2009, Part 2:2006, Part 3:2003,*
Part 5:2009, Part 7:2008, Part 10:2010, Part 11:2006, Part
18:2009 BS EN ISO 9001:2008
BS EN ISO 780 : 1999 BS EN ISO 11135: 2007

Authorised Signatory :
Name : Jane Hare
Position : SVP Healthcare Systems

Signed : 
Dated : 22nd April 2013
Certificate Reference HU/011 issue 015