

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 Post-Op/OPSITE Waterproof Dressings/OPSITE Plus

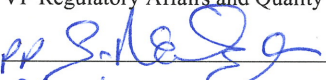
Classification : Class I Sterile
GMDN Code and Term : 34864 – Bandage, Adhesive
Scope of Application : All batches supplied to which the Declaration of Conformity Procedure has been applied.

Declaration : Conformity of the product has been assessed in accordance with Annex V and Annex VII of the Directive. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier of Technical Documentation.

Verification Certificate(s): EC Certificate No. CE 56481 Production 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 14971: 2012	BS EN ISO 11135:1-2014
BS EN ISO 9001: 2008	BS EN 13726-1: 2002
BS EN ISO 11607-1: 2009	BS EN ISO 11607-2:2006
BS EN 13726-2: 2002	BS EN 13726-3: 2003
BS EN ISO 780:1999	BS EN 1041: 2008
BS EN 556-1:2001/AC:2006	BS EN ISO 15223: 1-2012
BS EN ISO 10993:3-2009	BS EN ISO 10993-5:2009
BS EN ISO 10993-10:2013	BS EN ISO 10993-2:2006
BS EN ISO 10993-12:2012	BS EN ISO 10993-18: 2009
BS EN ISO 10993-1:2009/ AC:2010	
BS EN ISO 10993-7:2008/ AC:2009	
BS EN ISO 14644 -1:1999/AC: 2001	
BS EN ISO 13485: 2012	
EN 980:2008	

Authorised Signatory :
Name : Richard Wilkins
Position : VP Regulatory Affairs and Quality
Signed : 
Dated : 18/12/2014
Certificate Reference HU/002 issue 021