

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 GENTLE BORDER
ALLEVYN GENTLE BORDER HEEL
ALLEVYN GENTLE BORDER LITE
ALLEVYN GENTLE BORDER LITE OVAL
ALLEVYN GENTLE BORDER LITE MULTISITE
ALLEVYN GENTLE BORDER SACRUM
ALLEVYN GENTLE BORDER MULTISITE
Classification : Class IIb Sterile
GMDN Code and Term : 44970 Dressing, highly absorbent
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 14971: 2012
BS EN ISO 9001: 2008
BS EN ISO 13485: 2012
BS EN ISO 11607-1: 2009
BS EN 13726-1:2002
BS EN ISO 780:1999
BS EN 1041: 2008
BS EN ISO 10993-3:2009
BS EN ISO 10993-10:2013
BS EN ISO 10993-1:2009/ AC:2010
BS EN ISO 10993-2:2006
BS EN ISO 10993-7:2008/ AC:2009
BS EN ISO 10993-12:2012
BS EN ISO 14644 -1:1999/AC: 2001
BS EN ISO 11135:1-2014
BS EN 13726-2: 2002
BS EN 13726-3: 2003
BS EN 13726-4:2003
BS EN 15223-1: 2012
BS EN 556-1:2001/AC:2006
BS EN ISO 10993-5:2009
BS EN ISO 10993-18: 2009
Authorised Signatory :
Name : Richard Wilkins
Position : VP Regulatory Affairs & Quality
Signed : 
Dated : 24-12-2014
Certificate Reference HU/072 issue 049