

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 of 14th June 1993 (as amended)

Manufacturer's Name : Smith and Nephew Medical Limited
Business Address : 101 Hessle Road
Hull
HU3 2BN
United Kingdom

Medical Devices : BACTIGRAS

Classification : Class III

GMDN Code and Term : 47203 Dressings, wound-nonadherent, permeable, antimicrobial

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)

Design Examination Certificate: CE 01105

Standards Applied :

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|--------------------------------|--------------------------------|
| BS EN ISO 9001:2008 | BS EN ISO 10993-1:2009/AC:2010 |
| BS EN ISO 13485:2012 | BS EN ISO 10993-2:2006 |
| BS EN ISO 14971:2012 | BS EN ISO 10993-3:2009 |
| BS EN 556-1:2001/AC:2006 | BS EN ISO 10993-5:2009 |
| BS EN ISO 11137-1:2015 | BS EN ISO 10993-10:2013 |
| BS EN ISO 11137-2:2015 | BS EN ISO 10993-18:2009 |
| BS EN ISO 14644-1:1999/AC:2001 | BS EN ISO 15223-1:2012 |
| BS EN ISO 11607-1:2009 | BS EN 556-1:2001/AC:2006 |
| BS EN ISO 11607-2:2006 | |
| BS EN 980:2008 | |
| BS EN ISO 780:2015 | |
| BS EN ISO 1041:2008 | |

Authorised Signatory :

Name : Susan McLoughlin
Position : Director, Regulatory Affairs
Signed : 
27.07.2016

Dated :
Certificate Reference : DC 01 issue 11