Smith & Nephew Medical Limited
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Smith+Nephew

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
Authorised Representative:	Smith & Nephew Orthopaedics GmbH, Alemannenstraße 14, 78532 Tuttlingen, Germany
Medical Devices :	BACTIGRAS
Classification :	Class III
GMDN Code and Term :	47203 Wound non-adherent dressing, 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. 2797 (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 :	BS EN ISO 9001:2015 BS EN ISO 13485:2016 BS EN ISO 14971:2012 BS EN 556-1:2001/AC:2006 BS EN ISO 11137-1:2015 BS EN ISO 11137-2:2015 BS EN ISO 14644-1:2015 BS EN ISO 11607-1:2009 BS EN ISO 11607-2:2006 BS EN ISO 780:2015 BS EN 1041:2008 BS EN ISO 10993-1:2009/AC:2010 BS EN ISO 10993-2:2006 BS EN ISO 10993-3:2014 BS EN ISO 10993-5:2009 BS EN ISO 10993-10:2013 BS EN ISO 10993-18:2009 BS EN ISO 15223-1:2012

Authorised Signatory :

Name : STEEVE LAMVOHEE
Position : RA DIRECTOR
Signed :
Dated : 16-APR-2020
Certificate Reference : DC 01 Issue 14

Product Codes:

Code	Size
7456	5cm x 5cm
7457	10cm x 10cm
7461	15cm x 20cm
66003650	10cm x 10cm
66003661	10cm x 40cm
66007505	15cm x 1m roll