

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:	Acticoat Flex 3
Classification:	Class III
GMDN Code and Term:	47042 – Wound non-adherent dressing, absorbent, 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 547893
Standards Applied:	BS EN ISO 13485:2016 BS EN ISO 14971:2012 BS EN ISO 9001: 2015 BS EN 13726-4:2003 BS EN ISO 15223-1:2012 BS EN ISO 780:2015 BS EN 1041:2008 BS EN ISO 10993-1:2009 Oct 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

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BS EN 556-1:2001/AC:2006
BS EN ISO 11137-1:2015
BS EN ISO 11137-2:2015
BS EN ISO 11607-1:2009
BS EN ISO 14644-1:2015

Authorised Signatory:

Name:

H. M. MAY

Position:

SNR RA MANAGER

Signed:

Helen M. May

Dated:

9th APR 2019

Certificate Reference

DC 012, Issue 13

Product codes:

Code	Size
66800396	5cm x 5cm
66800398	10cm x 10cm
66800399	10cm x 10cm
66800409	10cm x 20cm
66800419	20cm x 40cm
66800432	40cm x 40cm
66800435	10cm x 120cm
66801290	4cm x 15cm
66801291	4cm x 25cm
66801292	4cm x 35cm
66801293	20cm x 20cm