Smith & Nephew Medical Limited
101 Hessle Road
Hull, HU3 2BN
England

T + 44 (0) 1482 225181
F + 44 (0) 1482 328326
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 & Nephew Medical Limited,
Business Address :	101 Hessle Road, Hull, HU3 2BN, United Kingdom.
Authorised Representative:	Smith & Nephew Orthopaedics GmbH, Alemannenstraβe 14, 78532 Tuttlingen, Germany
Medical Devices :	OPSITE Post-Op/ OPSITE waterproof Dressings/ OPSITE Plus
Classification :	Class I Sterile
GMDN Code and Term :	34864 -Adhesive bandage
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. 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)
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 11135:2014 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

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BS EN ISO 10993-3:2014
BS EN ISO 10993-5:2009
BS EN ISO 10993-7:2008/ AC:2009
BS EN ISO 10993-10:2013
BS EN ISO 10993-12:2012
BS EN ISO 10993-18:2009
BS EN 13726-1:2002
BS EN 13726-2:2002
BS EN 13726-3:2003
BS EN ISO 15223-1:2016
BS EN ISO 11737-1:2006/AC:2009
BS EN ISO 11737-2:2009

Authorised Signatory :

Name : STEVE LAMMONEE

Position : RA DIRECTOR

Signed :

Dated : 12-APR-2019

Certificate Reference : HU/002 issue 25

Product Codes:

Code	Size
66000762	12cm x 10cm
66000763	20cm x 10cm
66000764	35cm x 10cm
66000710	10cm x 12cm
66000713	20cm x 10cm
66000714	25cm x 10cm
66000715	30cm x 10cm
66000716	35cm x 10cm
66320803	25cm x 10cm
66800715	12cm x 10cm
66800716	30cm x 10cm
66800592	6.5cm x 5cm
66000600	6.5cm x 5cm
66240600	6.5cm x 5cm
66000708	6.5cm x 5cm
66030313	6.5cm x 5cm
66320600	6.5cm x 5cm
66800714	6.5cm x 5cm
66001381	6.5cm x 5cm
66801527	6.5cm x 5cm

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66000709	9.5cm x 8.5cm
66000712	15.5cm x 8.5cm
66001382	9.5cm x 8.5cm
66030314	9.5cm x 8.5cm
66320601	9.5cm x 8.5cm
66320802	15.5cm x 8.5cm
66000761	9.5cm x 8.5cm
66000762	12cm x 10cm
66000763	20cm x 10cm
66000764	35cm x 10cm
66000710	12cm x 10cm
66000713	20cm x 10cm
66000714	25cm x 10cm
66000715	30cm x 10cm
66000716	35cm x 10cm
66320803	25cm x 10cm
66800715	12cm x 10cm
66800716	30cm x 10cm

Registered No 605496 in England & Wales at PO Box 81, 101 Hessle Road, Hull HU3 2BN. Smith & Nephew Medical Limited, acting as agent for T J Smith and Nephew,Limited