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

T + 44 (0) 1482 225181
F + 44 (0) 1482 328326
www.smith-nephew.com

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 (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,
Alemannenstraße 14,
78532 Tuttlingen,
Germany

Medical Devices : DURAFIBER

Classification : Class IIb

GMDN Code and Term : 43186 – Exudate-absorbent dressing, hydrophilic-gel, sterile

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)

Standards Applied:

BS EN ISO 13485:2016
BS EN ISO 9001:2015
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+A1:2014
BS EN ISO 11607-2: 2006+A1:2014
BS EN ISO 780:2015
BS EN 1041:2008
BS EN ISO 10993-1:October 2009
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 10993-12:2012
BS EN ISO 10993-18:2009
BS EN 13726-1: 2002/AC:2003
BS EN 13726-4:2003
BS EN ISO 15223-1:2016
BS EN ISO 11737-1:2006/ AC:2009
BS EN ISO 11737-2:2009

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Product Codes:

Code	Size
66800559	5cm x 5cm
66800560	10cm x 10cm
66800551	10cm x 12cm
66800561	15cm x 15cm
66800563	2cm x 45cm
66800546	4cm x 10cm
66800547	4cm x 20cm
66800548	4cm x 30cm
66800029	5cm x 5cm
66800030	10cm x 10cm
66800031	15cm x 15cm
66800033	2cm x 45cm
66800029S	5cm x 5cm

Authorised Signatory :

Name : H. M. MAY

Position : SNR REG'Y AFFAIRS MANAGER

Signed : Helen M. May

Dated : 12 JULY 2019

Certificate Reference : HU/145 issue 010

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.