

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

SmithNephew

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 : OPSITE

Classification : Class IIa Sterile
GMDN Code and Term : 47783 Surgical Drape, general purpose, single use, 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 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 780:2015
BS EN 1041:2008
BS EN ISO 10993-1:2018
BS EN ISO 10993-3:2014
BS EN ISO 10993-5:2009

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BS EN ISO 10993-7:2008/AC:2009
BS EN ISO 10993-10:2013
BS EN ISO 10993-18:2009
BS EN 13726-2:2002
BS EN 13726-3:2003
BS EN ISO 15223-1:2016

PRODUCT CODES

Code	Size
4988	28cm x 45cm dressing
4995	42cm x 40cm dressing
4989	55cm x 45cm dressing
4994	84cm x 56cm dressing
4963	10cm x 14cm dressing
4975	14cm x 10cm dressing
4986	15cm x 28cm dressing
4987	30cm x 28cm dressing
4542	28cm x 10cm dressing
4967	14cm x 25cm dressing

Authorised Signatory :

Name :

KEN FERCUSSON

Position :

REGULATORY AFFAIRS MANAGER

Signed :

Dated :

16 OCT 2020

Certificate Reference :

HU/069 issue 18