

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

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: ALLEVYN Ag Gentle Border

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: *Handwritten signature*
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 Institution)
British Standards Institution. Certificate No. MD 76718
Quality Management System (BS EN ISO 13485)
British Standards Institution. Certificate No. FM 24676
Quality Management System (BS EN ISO 9001)

**Design Examination
Certificate** CE 518880

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Standards Applied:

BS EN ISO 13485:2016	BS EN ISO 14971:2012
BS EN ISO 9001:2015	BS EN ISO 13726- 1:2002/AC:2003
BS EN ISO 13726-2:2002	BS EN ISO 13726-3:2003
BS EN ISO 13726-4:2003	BS EN ISO 780:2015
BS EN ISO 15223-1:2012	BS EN 1041:2008
BS EN ISO 10993-1:2009	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 10993-18:2009
BS EN 556-1:2001/AC:2006	BS EN 11135:2014
BS EN ISO 11607-1:2009	BS EN ISO 11607-2:2006
BS EN ISO 14644- 1:1999/AC:2001	

Product Codes:

Code	Size
66800436	7.5cm x 7.5cm (International)
66800460	7.5cm x 7.5cm (UK Only)
66800437	10cm x 10cm (International)
66800461	10cm x 10cm (UK Only)
66800438	12.5cm x 12.5cm (International)
66800462	12.5cm x 12.5cm (UK Only)
66800439	17.5cm x 17.5cm (International)
66800463	17.5cm x 17.5cm (UK Only)

Authorised Signatory:

Name:

Helen M. May

Position:

snr Regulatory
Affairs Manager

Signed:

15th April 2020

Dated:

Certificate Reference:

DC 010/09 Issue 21

BS EN 13726 Part 1: 2002/AC:2003
BS EN 13726 Part 2: 2002
BS EN 13726 Part 3: 2003
BS EN 13726 Part 4: 2003
BS EN ISO 15223:2012

Authorised Signatory :

Name : STEELE LAMVORRE

Position : RA DIRECTOR

Signed



Dated :

19- SEP - 2019

Certificate Reference

HU/005 issue 39