

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

T: + 44 (0)1482 225181
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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 Adhesive
ALLEVYN Ag Sacrum
ALLEVYN Silber Schaumverband Haftend

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 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

DC 010/02 Issue 19

Certificate Reference:

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Smith+Nephew**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 11137:2015

BS EN ISO 11607-1:2009

BS EN ISO 11607-2:2006

BS EN ISO 14644-1:2015

Product Codes:**ALLEVYN Ag Adhesive**

Code	Size	Code	Size
66800072	7.5cm x 7.5cm (International)	66800073	7.5cm x 7.5cm (UK Only)
66800074	10cm x 10cm (International)	66800075	10cm x 10cm (UK Only)
66800076	12.5cm x 12.5cm (International)	66800078	12.5cm x 12.5cm (UK Only)
66800080	17.5cm x 17.5cm (International)	66800081	17.5cm x 17.5cm (UK Only)

ALLEVYN Ag Sacrum

Code	Size	Code	Size
66800092	17cm x 17cm (International)	66800094	17cm x 17cm (UK Only)
66800095	22cm x 22cm (International)	66800097	22cm x 22cm (UK Only)

ALLEVYN Silber Schaumverband Haftend

Code	Size	Code	Size
66801122	7cm x 8cm	66801131	7cm x 8cm
66801123	9cm x 11cm	66801132	9cm x 11cm
66801124	12cm x 13cm	66801133	12cm x 13cm
66801125	17cm x 18cm	66801134	17cm x 18cm

Authorised Signatory:**Name:**Helen M. May**Position:**Snr Regulatory
Affairs Manager**Signed:****Dated:**15th April 2020**Certificate Reference:**DC 010/02 Issue 19