

EUROPEAN DECLARATION OF CONFORMITY

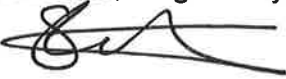
This Declaration confirms that the product listed below meets the Essential Requirements set out in Annex I of the Council Directive 93/42/EEC (as amended).

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 Non-Adhesive
Classification :	Class IIb
GMDN Code and Term :	44970 - Exudate-absorbent dressing, non-gel
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 10993-1:2009/AC:2010
BS EN ISO 13485:2016	BS EN ISO 10993-3:2014
BS EN ISO 14971:2012	BS EN ISO 10993-5:2009
BS EN 556-1:2001/AC:2006	BS EN ISO 10993-10:2013
BS EN ISO 11137-1:2015	BS EN ISO 10993-12:2012
BS EN ISO 11137-2:2015	BS EN ISO 10993-18:2009
BS EN ISO 11737-1:2006/AC:2009	BS EN 13726-1:2002/AC: 2003
BS EN ISO 14644-1:2015	BS EN 13726-2: 2002
BS EN ISO 11607-1: 2009	BS EN 13726-3: 2003
BS EN ISO 11607-2:2006	BS EN 13726-4: 2003
BS EN ISO 780:2015	BS EN ISO 15223-1:2016
BS EN ISO 1041: 2008	

Authorised Signatory :

Name : Steve Lamvohee
Position : Director, Regulatory Affairs
Signed : 
Dated : 29-MAR-2019
Certificate Reference : HU/008 issue 38

Products manufactured by S&N Medical Ltd., Hull, UK:

ALLEVYN NON-ADHESIVE

66000663	70cm x 40cm dressing
66007637	10cm x 10cm dressing

ALLEVYN HEEL

Products manufactured by S&N Medical Ltd., Hull, UK:

66007630	Heel Dressing
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Products manufactured by S&N Medical (Suzhou) Ltd., China:

66000695	Heel Dressing
66007630	Heel Dressing
66800021	Heel Dressing
66000773	Heel Dressing
66801121	Heel Dressing (ALLEVYN Schaumverband Ferse Nicht Haftend)
66801150	Heel Dressing (ALLEVYN Schaumverband Ferse Nicht Haftend)

ALLEVYN Non-Adhesive

Code	Size
66000092	20cm x 20cm dressing
66000093	15cm x 15cm dressing
66000352	10cm x 10cm dressing
66000353	15cm x 15cm dressing
66007335	10cm x 20cm dressing
66007637	10cm x 10cm dressing
66007638	20cm x 20cm dressing
66007643	5cm x 5cm dressing
66007670	15cm x 15cm dressing
66157335	10cm x 20cm dressing
66157637	10cm x 10cm dressing
66157638	20cm x 20cm dressing
66157643	5cm x 5cm dressing
66320769	10cm x 20cm dressing
66320870	21.5cm x 21.5cm dressing
66320871	11cm x 11cm dressing
66800013	15cm x 15cm dressing
66800020	10cm x 20cm dressing
66800022	10cm x 10cm dressing
66800023	20cm x 20cm dressing
66800024	5cm x 5cm dressing
66801116	4.5cm x 5.5cm (ALLEVYN Schaumverband Nicht Haftend)
66801117	9cm x 11cm (ALLEVYN Schaumverband Nicht Haftend)

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6680118	9cm x 21cm (ALLEVYN Schaumverband Nicht Haftend)
6680119	14cm x 16cm (ALLEVYN Schaumverband Nicht Haftend)
6680120	19cm x 21cm (ALLEVYN Schaumverband Nicht Haftend)
6680145	4.5cm x 5.5cm (ALLEVYN Schaumverband Nicht Haftend)
6680146	9cm x 11cm (ALLEVYN Schaumverband Nicht Haftend)
6680147	9cm x 21cm (ALLEVYN Schaumverband Nicht Haftend)
6680148	14cm x 16cm (ALLEVYN Schaumverband Nicht Haftend)
6680149	19cm x 21cm (ALLEVYN Schaumverband Nicht Haftend)
66000663	70cm x 40cm dressing