

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 Sterile	
GMDN Code and Term:	44970 – Exudate-absorbent dressing, non-gel, non-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)	
Standards Applied:	BS EN ISO 9001:2015 BS EN ISO 13485:2016 BS EN ISO 14971:2019 BS EN 556-1:2001/AC:2006 BS EN ISO 11137-1:2015 BS EN ISO 11137-2:2015	BS EN ISO 10993-1:2018 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 ISO 11737-1:2006 / AC:2009 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 13726- 1:2002/AC:2003 BS EN 13726-2:2002 BS EN 13726-3:2003 BS EN 13726-4:2003 BS EN ISO 15223-1:2016
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Product Codes:

**Product made by S&N Medical Limited, Hull UK
ALLEVYN Non-Adhesive**

Code	Size	Carton Quantity	Languages on the insert leaflet	Other Information
66000663	70cm x 40cm dressing	carton of 2	FR, ES, IT, NL, GR, DK, NO, FI, SE, PT, TR, PL, EN	
66007637	10cm x 10cm dressing	carton of 10	FR, ES, IT, NL, GR, DK, NO, FI, SE, PT, TR, PL, EN	Standard

**Products made by S&N Medical (Suzhou) Limited
ALLEVYN Non-Adhesive**

Code	Size	Carton Quantity	Languages on the insert leaflet	Other Information
66000092	20cm x 20cm dressing	carton of 3	EN, FR, DE, ES, IT, NL, GR, DK, NO, FI, SE, PT, BG, CZ, EE, HU, LT, LV, PL, RO, RU, SI, SK, TR	Spanish reimbursement
66000093	15cm x 15cm dressing	carton of 10	FR, ES, IT, NL, GR, DK, NO, FI, SE, PT, TR, PL, EN	Standard
66000352	10cm x 10cm dressing	carton of 3	EN, FR, DE, ES, IT, NL, GR, DK, NO, FI, SE, PT, BG, CZ, EE, HU, LT, LV, PL, RO, RU, SI, SK, TR	Spanish reimbursement
66000353	15cm x 15cm dressing	carton of 3	EN, FR, DE, ES, IT, NL, GR, DK, NO, FI, SE, PT, BG, CZ, EE, HU, LT, LV, PL, RO, RU, SI, SK, TR	Spanish reimbursement
66007335	10cm x 20cm dressing	carton of 10	FR, ES, IT, NL, GR, DK, NO, FI, SE, PT, TR, PL, EN	Standard
66007637	10cm x 10cm dressing	carton of 10	FR, ES, IT, NL, GR, DK, NO, FI, SE, PT, TR, PL, EN	Standard


66007638	20cm x 20cm dressing	carton of 10	FR, ES, IT, NL, GR, DK, NO, FI, SE, PT, TR, PL, EN	Standard
66007643	5cm x 5cm dressing	carton of 10	FR, ES, IT, NL, GR, DK, NO, FI, SE, PT, TR, PL, EN	Standard
66007670	15cm x 15cm dressing	carton of 5	EN, FR, DE, ES, IT, NL, GR, DK, NO, FI, SE, PT, BG, CZ, EE, HU, LT, LV, PL, RO, RU, SI, SK, TR	Reimbursement in Sicily, Italy
66157335	10cm x 20cm dressing	carton of 10	EN	UK Drug Tariff
66157637	10cm x 10cm dressing	carton of 10	EN	UK Drug Tariff
66157638	20cm x 20cm dressing	carton of 10	EN	UK Drug Tariff
66157643	5cm x 5cm dressing	carton of 10	EN	UK Drug Tariff
66320769	10cm x 20cm dressing	carton of 16	FR	French Reimbursement
66320870	21.5cm x 21.5cm dressing	carton of 10	FR	French Reimbursement
66320871	11cm x 11cm dressing	carton of 16	FR	French Reimbursement
66800013	15cm x 15cm dressing	carton of 10	NL, IT, DE, FR	Four Language Pack Austria, Belgium, Italy, Switzerland
66800020	10cm x 20cm dressing	carton of 10	NL, IT, DE, FR	Four Language Pack Austria, Belgium, Italy, Switzerland
66800022	10cm x 10cm dressing	carton of 10	NL, IT, DE, FR	Four Language Pack Austria, Belgium, Italy, Switzerland
66800023	20cm x 20cm dressing	carton of 10	NL, IT, DE, FR	Four Language Pack Austria, Belgium, Italy, Switzerland

66800024	5cm x 5cm dressing	carton of 10	NL, IT, DE, FR	Four Language Pack Austria, Belgium, Italy, Switzerland
66801116	4.5cm x 5.5cm (ALLEVYN Schaumverband Nicht Haftend)	carton of 12	DE	German only
66801117	9cm x 11cm (ALLEVYN Schaumverband Nicht Haftend)	carton of 12	DE	German only
66801118	9cm x 21cm (ALLEVYN Schaumverband Nicht Haftend)	carton of 12	DE	German only
66801119	14cm x 16cm (ALLEVYN Schaumverband Nicht Haftend)	carton of 12	DE	German only
66801120	19cm x 21cm (ALLEVYN Schaumverband Nicht Haftend)	carton of 12	DE	German only
66801145	4.5cm x 5.5cm (ALLEVYN Schaumverband Nicht Haftend)	carton of 20	DE	German only
66801146	9cm x 11cm (ALLEVYN Schaumverband Nicht Haftend)	carton of 20	DE	German only
66801147	9cm x 21cm (ALLEVYN Schaumverband Nicht Haftend)	carton of 20	DE	German only
66801148	14cm x 16cm (ALLEVYN Schaumverband Nicht Haftend)	carton of 20	DE	German only

66801149	19cm x 21cm (ALLEVYN Schaumverband Nicht Haftend)	carton of 20	DE	German only
66000663	70cm x 40cm dressing	carton of 2	FR, ES, IT, NL, GR, DK, NO,FI, SE, PT, TR, PL, EN	

ALLEVYN Heel

Code	Size	Carton Quantity	Languages on the insert leaflet	Other Information
66000695	Heel Dressing	carton of 3		
66007630	Heel Dressing	carton of 5	FR, ES, IT, NL, GR, DK, NO,FI, SE, PT, TR, PL, EN	Standard
66800021	Heel Dressing	carton of 5	NL, IT, DE, FR	Four Language Pack Austria, Belgium, Italy, Switzerland
66000773	Heel Dressing	carton of 10	FR, ES, IT, NL, GR, DK, NO,FI, SE, PT, TR, PL, EN	
66801121	Heel Dressing (ALLEVYN Schaumverband Ferse Nicht Haftend)	carton of 7	DE	German only
66801150	Heel Dressing (ALLEVYN Schaumverband Ferse Nicht Haftend)	carton of 10	DE	German only

Authorised Signatory Name:	KEN FERGUSSON
Position:	SENIOR REGULATORY AFFAIRS MANAGER
Signed:	
Dated:	05 FEB 2021
Certificate Reference:	HU/008 Issue 039