

## 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 LIFE

**Classification :** Class IIb Sterile  
**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 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 10993-3:2014
BS EN ISO 13485: 2016	BS EN ISO 10993-5:2009
BS EN ISO 14971: 2012	BS EN ISO 10993-7:2008/ AC:2009
BS EN 556-1:2001/AC:2006	BS EN ISO 10993-10:2013
BS EN ISO 11135: 2014	BS EN ISO 10993-11:2009
BS EN ISO 14644 -1:2015	BS EN ISO 10993-18: 2009
BS EN ISO 11607-1: 2009	BS EN 13726-1:2002/AC:2003
BS EN ISO 11607-2: 2006+A1:2014	BS EN 13726-2: 2002
BS EN ISO 780:2015	BS EN 13726-3: 2003

BS EN 1041: 2008  
BS EN ISO 10993-1: 2009/AC:2010  
BS EN ISO 10993-2:2006  
BS EN ISO 11737-1:2006/AC:2009

BS EN 13726-4:2003  
BS EN ISO 15223-1:2016  
ISTA 2A: 2011  
BS EN ISO 11737-2:2015

**Authorised  
Signatory :**

**Name :** Steeve Lamvohee

**Position :** Director, Regulatory Affairs

**Signed :**



**Dated :**

25-MAR-2020

**Certificate  
Reference :** HU/062 issue 31

Manufactured in Hull, UK	
Code	Size
66801067	10.3cm x 10.3cm
66801068	12.9cm x 12.9cm
66801068s	12.9cm x 12.9cm
66801068sd	12.9cm x 12.9cm
66801068sf	12.9cm x 12.9cm
66801068sn	12.9cm x 12.9cm
66801069	15.4 cm x 15.4 cm
66801070	21 cm x 21 cm
66801080	10.7cm x 10.7cm
66801081	15.4 cm x 15.4 cm
66801306	17.2 x 17.5cm (Small sacrum)
66801307	21.6 x 23cm (Large sacrum)
66801067s	10.3cm x 10.3cm
66801067SGB	10.3cm x 10.3cm
66801304	Heel
66801305	Heel
66021067	10.3cm x 10.3cm
66021068	12.9cm x 12.9cm
66021069	15.4cm x 15.4cm
66021070	21cm x 21cm
66021304	Heel
66021306	17.2 x 17.5cm (Small sacrum)
66021307	21.6 x 23cm (Large sacrum)
66803091	12.9cm x 12.9cm

Manufactured in Suzhou, China	
Code	Size
66801067	10.3cm x 10.3cm
66801068	12.9cm x 12.9cm
66801069	15.4 cm x 15.4 cm
66801070	21 cm x 21 cm
66801080	10.7cm x 10.7cm
66801081	15.4 cm x 15.4 cm
66801067s	10.3cm x 10.3cm
66801304	Heel
66801305	Heel
66801306	17.2 x 17.5cm (Small sacrum)
66801307	21.6 x 23cm (Large sacrum)
66801742	15.4cm x 15.4cm
66801743	21cm x 21cm