

## 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).

<b>Manufacturer's Name :</b>	Smith & Nephew Medical Limited
<b>Business Address:</b>	101 Hessle Road, Hull, HU3 2BN, United Kingdom.
<b>Authorised Representative:</b>	Smith & Nephew Orthopaedics GmbH, Alemannenstraße 14, 78532 Tuttlingen, Germany
<b>Medical Devices:</b>	ALLEVYN GENTLE BORDER LITE ALLEVYN GENTLE BORDER LITE OVAL ALLEVYN GENTLE BORDER LITE MULTISITE
<b>Classification:</b>	Class IIb Sterile
<b>GMDN Code and Term:</b>	44970 Exudate-absorbent dressing, non-gel
<b>Scope of Application:</b>	All batches supplied to which the Declaration of Conformity Procedure has been applied.
<b>Declaration:</b>	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.
<b>Verification Certificate(s):</b>	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)
<b>Standards Applied:</b>	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 11135:2014/A1:2019  
 BS EN ISO 14644 -1:2015  
 BS EN ISO 11607-1:2017  
 BS EN ISO 11607-2:2009  
 BS EN ISO 11737-1:2018  
 BS EN ISO 11737-2:2020  
 BS EN ISO 780:2015  
 BS EN ISO 10993-1:2020  
 BS EN ISO 10993-2:2006  
 BS EN ISO 10993-3:2014  
 BS EN ISO 10993-5:2009  
 BS EN ISO 10993-7:2008  
 BS EN ISO 10993-10:2013  
 BS EN ISO 10993-12:2021  
 BS EN ISO 10993-18:2020  
 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  
 BS EN ISO 20417:2021

**Product Codes:**

SKU	Size
66800834	7.5 cm x 7.5cm
66800835	10cm x 10cm
66800836	5.5cm x 12cm
66800837	8cm x 15cm
66800840	15cm x 15cm
66800841	8cm x 8cm
66801012	10cm x 20cm
66800833	5cm x 5cm
66801013	8.6cm x 7.7cm (Oval)
66801014	15.2cm x 13.1cm (Oval)
66801041	8cm x 8.4cm (Multisite)
66800834s	7.5cm x 7.5cm
66801887	10cm x 20cm
66801888	8.6cm x 7.7cm (Oval)
66802143	8.6cm x 7.7cm (Oval)
66802144	8cm x 8.4cm (Multisite)

Smith & Nephew Medical Ltd.  
101 Hessle Road  
Hull, HU3 2BN  
England

T + 44 (0) 1482 225181  
F + 44 (0) 1482 328326  
www.smith-nephew.com

# Smith+Nephew

**Authorised Signatory:**

**Name:**

KEN FERGUSON

**Position:**

SENIOR REGULATORY AFFAIRS MANAGER

**Signed:**

**Dated:**



17 MAR 2022

**Certificate Reference:**

HU/163 Issue 04