

## 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 Hesse Road,  
Hull,  
HU3 2BN,  
United Kingdom.

**Authorised Representative:** Smith & Nephew Orthopaedics GmbH,  
Alemannenstraße 14,  
78532 Tuttlingen,  
Germany

**Medical Devices :** ALLEVYN GENTLE BORDER  
ALLEVYN GENTLE BORDER HEEL  
ALLEVYN GENTLE BORDER SACRUM  
ALLEVYN GENTLE BORDER MULTISITE

**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 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 1041: 2008+A1:2013 |
| BS EN ISO 13485:2016         | BS EN ISO 10993-1:2009   |
| BS EN ISO 14971:2012         | BS EN ISO 10993-2:2006   |
| BS EN 556-1:2001/AC:2006     | BS EN ISO 10993-3:2014   |
| BS EN ISO 11135:2014/A1:2019 | BS EN ISO 10993-5:2009   |
| BS EN ISO 14644 -1:2015      | BS EN ISO 10993-10:2013  |
|                              | BS EN ISO 10993-7:2008   |

BS EN ISO 11607-2:2009  
BS EN ISO 11737-1:2018  
BS EN ISO 780:2015  
BS EN ISO 15223-1:2016

BS EN ISO 10993-18:2009  
BS EN 13726-1:2002/AC:2003  
BS EN 13726-2: 2002  
BS EN 13726-3: 2003  
BS EN 13726-4:2003

**PRODUCT CODES**

| SKU      | Size            | SKU      | Size            |
|----------|-----------------|----------|-----------------|
| 66800259 | 7.5cm x 7.5cm   | 66800901 | 10cm x 20cm     |
| 66800260 | 10cm x 10cm     | 66800264 | 10cm x 25cm     |
| 66800262 | 12.5cm x 12.5cm | 66800265 | 10cm x 30cm     |
| 66800263 | 17.5cm x 17.5cm | 66800506 | Heel dressing   |
| 66800269 | 7.5cm x 7.5cm   | 66800507 | Heel dressing   |
| 66800270 | 10cm x 10cm     | 66800897 | 16.8cm x 17.1cm |
| 66800272 | 12.5cm x 12.5cm | 66800898 | 16.8cm x 17.1cm |
| 66800273 | 17.5cm x 17.5cm | 66800899 | 16.8cm x 17.1cm |
| 66800274 | 8cm x 8cm       | 66801031 | 21.6cm x 23cm   |
| 66800275 | 12.5cm x 12.5cm | 66800959 | 17.1cm x 17.9cm |
| 66800975 | 15cm x 15cm     | 66800960 | 17.1cm x 17.9cm |
| 66800900 | 10cm x 20cm     | 66802142 | 12.5cm x 12.5cm |

**Authorised Signatory :**

**Name :** STEVE LAMVOLEE

**Position :** RA DIRECTOR

**Signed :** 

**Dated :** 26 - FEB - 2021

**Certificate Reference :** HU/072 issue 61