

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