

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 LITE ALLEVYN GENTLE BORDER LITE OVAL ALLEVYN GENTLE BORDER LITE 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 ISO 13485:2016 BS EN ISO 14971:2012 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 780:2015
BS EN 1041: 2008+A1:2013
BS EN ISO 10993-1:2009
BS EN ISO 10993-2:2006
BS EN ISO 10993-3:2014
BS EN ISO 10993-5:2009
BS EN ISO 10993-10:2013
BS EN ISO 10993-7:2008
BS EN ISO 10993-12:2012
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
BS EN ISO 15223-1:2016

Product Code(s):

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)

Authorised Signatory :

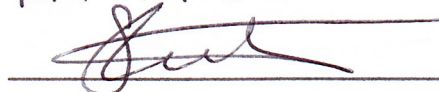
Name :

STEVE LAMICHEE

Position :

RA DIRECTOR

Signed :



Dated :

08-NOV-2020

Certificate Reference :

HU/162 issue 02