

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 : Jelonet

Classification : Class IIa
GMDN Code and Term : 46855 Wound-non-adherent dressing, permeable
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)

Standards Applied : British Standards Institute. Certificate No. FM 24676 Quality Management System (BS EN ISO 9001)
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 11137-1:2015
BS EN ISO 11137-2:2015
BS EN ISO 11737-1:2006/AC:2009
BS EN ISO 11737-2:2009
BS EN ISO 14644 -1:2015
BS EN ISO 11607-1: 2009

EN ISO 780:2015
BS EN ISO 1041: 2008
BS EN ISO 10993-1:2009/AC:2010
BS EN ISO 10993-5:2009
BS EN ISO 10993-10:2013
BS EN ISO 15223-1:2012

Authorised Signatory :

Name :

STEELE LAMUONEE

Position :

RA DIRECTOR

Signed :



Dated :

16-APR-2019

Certificate Reference :

HU/035 issue 18

PRODUCT CODES

Code	Size
Jelonet Pouch	
7403	5cm x 5cm
7404	10cm x 10cm
7409	10cm x 10cm
7415	15cm x 2m on a roll
7459	10cm x 40cm
66007450	10cm x 10cm
Consumer Select	
66320338	10cm x 10cm
66320572	5cm x 5cm
66000678	5cm x 5cm
Menat Retail Pack	
66801534	10cm x 10cm