

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 : MELOLIN
CUTILIN
Classification : Class I Sterile
GMDN Code and Term : 46854 Wound Non-Adherent Dressing, Absorbent

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 V and Annex VII of the Directive. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier of Technical Documentation.

Verification Certificate(s): EC Certificate No. CE 56481 Production 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 ISO 17665-1:2006
BS EN ISO 780:2015	BS EN ISO 15223-1:2016
BS EN ISO 10993-5:2009	BS EN ISO 10993-7:2008
BS EN ISO 10993-10:2013	BS EN 556-1:2001/AC:2006
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+A1:2014	
BS EN ISO 11607-2:2006+A1:2014	BS EN 1041:2008

Authorised Signatory :

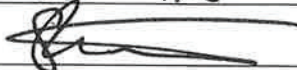
Name :

STERIE LAMVOUÉE

Position :

RA DIRECTOR

Signed :



Dated :

16-APR-2019

Certificate Reference :

HU/007 issue 23

Product Codes

MELOLIN

Code	Size
Non-Sterile	
66974930	50cm x 7m
66974942	10cm x 10cm
66974943	10cm x 20cm
66974944	20cm x 30cm
Sterile	
66964941	10cm x 10cm
66964940	5cm x 5cm
66964939	20cm x 10cm
66974932	5cm x 5cm
66974933	10cm x 10cm
66974939	20cm x 10cm
66974940	5cm x 5cm
66974941	10cm x 10cm
36361357	5cm x 5cm
36361358	10cm x 10cm
36101013	5cm x 5cm
36101113	10cm x 10cm
36101213	10cm x 20cm
66801536	10cm x 10cm
Consumer Select Sterile	
66000381	5cm x 5cm
66000382	10cm x 10cm
66000603	10cm x 10cm
66030260	5cm x 5cm
66030261	10cm x 10cm
66800707	10cm x 20cm
66965755	5cm x 5cm Numark
66965756	10cm x 10cm Numark
66965757	20cm x 10cm Numark
66000602	5cm x 5cm
66240261	10cm x 10cm
66240602	5cm x 5cm

Product Codes

CUTILIN

Code	Size
76240	5cm x 5cm
76242	10cm x 10cm
76243	10cm x 20cm
36361374	5cm x 5cm
36361375	10cm x 10cm
76238	45cm x 7m

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Medical Devices : MELOLIN
CUTILIN

Classification : Class I Non-sterile

GMDN Code and Term : 46854 Wound Non-Adherent Dressing, Absorbent

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 VII of the Directive. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier of Technical Documentation.

Verification Certificate(s): British Standards Institute. Certificate No. MD 76718 Quality Management System (BS EN ISO 13485)
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BS EN ISO 10993-5:2009	BS EN ISO 10993-7:2008
BS EN ISO 10993-10:2013	BS EN 556-1:2001/AC:2006
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+A1:2014	
BS EN ISO 11607-2:2006+A1:2014	BS EN 1041:2008

Authorised Signatory :

Name :

STEVE LAMVORRE

Position :

RA DIRECTOR

Signed :



Dated :

16- APR - 2019

Certificate Reference :

HU/007 issue 23

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