Smith & Nephew Medical Ltd.
101 Hessle Road
Hull, HU3 2BN
England

T + 44 (0) 1482 225181
F + 44 (0) 1482 328326
www.smith-nephew.com

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 :	PRIMAPORE MELOLIN Adhesive
Classification :	Class I Sterile
GMDN Code and Term :	34864 Bandage, adhesive
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 556-1:2001/AC:2006 BS EN ISO 11135:2014 BS EN ISO 780:2015 BS EN 1041:2008 BS EN ISO 10993-1:October 2009 BS EN ISO 10993-5:2009 BS EN ISO 10993-7:2008 BS EN ISO 10993-18:2009 BS EN ISO 15223-1:2016 BS EN ISO 11607-1:2009+A1:2014 BS EN ISO 11737-1:2018 BS EN ISO 14644-1:2015

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Authorised Signatory :
Name : STEEVE LAMLOMEE

Position : RA DIRECTOR

Signed :

Dated : 28-MAR-2019
Certificate Reference : HU/001 issue 12

PRODUCT CODES

PRIMAPORE

7127	8.3cm x 6cm
7133	7.2cm x 5cm
7135	8.3cm x 6cm
66000317	10cm x 8cm
66000318	15cm x 8cm
66000319	20cm x 10cm
66000320	25cm x 10cm
66000321	30cm x 10cm
66003634	7.2cm x 5cm
66007140	35cm x 10cm
66030263	10cm x 8cm
66240653	8.3cm x 6cm
66030262	8.3cm x 6cm
66801530	8.3cm x 6cm
66801531	10cm x 8cm

MELOLIN Adhesive

66000654	10cm x 8cm
66000653	8.3cm x 6cm

Registered No. 605496 in England & Wales at PO Box 81, 101 Hessle Road, Hull HU3 2BN. Smith & Nephew Medical Limited, acting as agent for T.J.Smith and Nephew, Limited.