Smith & Nephew Medical Ltd.
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England

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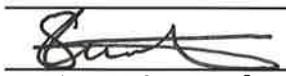
smith&nephew

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, Alemannenstraβe 14, 78532 Tuttlingen, Germany
Medical Devices :	OPSITE Spray
Classification :	Class I Non-sterile
GMDN Code and Term :	58978 – Synthetic- polymer liquid barrier dressing, non-sterile
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) British Standards Institute. Certificate No. FM 24676 Quality Management System (BS EN ISO 9001)
Standards Applied :	BS EN ISO 14971:2012 BS EN ISO 9001:2015 BS EN ISO 13485:2016 BS EN ISO 780:2015 Regulation (EC) No 1272/2008 Council directive 80/232/EEC Aerosol directive 75/324/EEC and amendment 94/1/EC BS EN 1041:2008 BS EN ISO 10993 - 1:2018 BS EN ISO 10993 - 10:2010 BS EN ISO 15223-1:2012 BS EN ISO 14644-1:2015

Authorised Signatory :

Name :	STEVE LAMMOLEE
Position :	RA DIRECTOR
Signed :	
Dated :	21-MAR-2019
Certificate Reference :	HU/040 issue 010

PRODUCT CODES

Code	Size
66004978	100ml
66004979	100ml
66004980	240ml
66800653	*240ml*
Consumer Select	
66000679	40ml