Smith & Nephew Medical Ltd.
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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 :	CICA-CARE
Classification :	Class I Non-sterile
GMDN Code and Term :	44898 Scar Management dressing, reusable
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 9001:2015	BS EN ISO 10993-12:2012
BS EN ISO 13485:2016	BS EN ISO 10993-18:2009
BS EN ISO 10993-1:2009/AC:2010	BS EN ISO 14971:2012
BS EN ISO 10993-2:2006	BS EN ISO 780:2015
BS EN ISO 10993-3:2014	BS EN ISO 15223-1:2012
BS EN ISO 10993-5:2009	BS EN 1041: 2008+A1:2013
BS EN ISO 10993-10:2013	BS EN ISO 14644 -1:2015

Authorised Signatory :

Name :	STEEVE LAFNOUEE
Position :	RA DIRECTOR
Signed :	
Dated :	16-APR-2019
Certificate Reference :	HU/067 issue 015

PRODUCT CODES

Code	Size
66250707	12cm x 15cm
66250706	12cm x 15cm
66250704	12cm x 6cm
66000702	12cm x 6cm
66320703	12cm x 6cm
66250705	12cm x 6cm
66030702	12cm x 6cm
66801535	6cm x 12cm
66801854	12cm x 3cm