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

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, Alemannenstraße 14, 78532 Tuttlingen, Germany
Medical Devices :	INTRASITE Gel
Classification :	Class IIb Sterile
GMDN Code and Term :	47764 – Wound Hydrogel Dressing, 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 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) 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 11737 - 1:2006/AC:2009 BS EN ISO 17665-1:2009 BS EN ISO 14644 -1:2016 BS EN ISO 11607-1: 2009 BS EN ISO 780:2015 BS EN ISO 10993-5:2009

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BS EN ISO 10993-12:2012
BS EN ISO 10993-1:2009/AC:2010
BS EN ISO 15223-1:2012

Authorised Signatory :

Name : pp Steeve Lamvohee

Position : Director, Regulatory Affairs

Signed : Helen M. May, SNR RA MANAGER

Dated : 29th MAR 2019

Certificate Reference : HU/038 issue 13

Product Codes

Code	Size
7308	8g Applipak
7311	15g Applipak
7313	25g Applipak
66157417	15g Applipak
66000240	15g Applipak
66800241	25g Applipak