

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 : SECURA NO-STING Barrier Film Spray
Classification : Class I Sterile

GMDN Code and Term : 58979: Synthetic-polymer liquid barrier dressing, sterile

Scope of Application : All batches supplied to which the Declaration of Conformity Procedure has been applied.

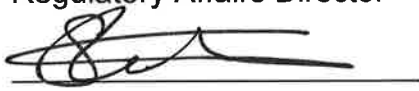
Declaration : Conformity of the product has been assessed in accordance with Annex V and Annex VII of the Directive. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier of Technical Documentation.

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 1041: 2008
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 11137-1:2015
BS EN ISO 11137-2:2015
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 ISO 780:2015

BS EN 1041:2008
BS EN ISO 10993-1:October 2009
BS EN ISO 10993-3:2014
BS EN ISO 10993-5:2009
BS EN ISO 10993-10:2013
BS EN ISO 15223-1:2016
The Classification, Labelling and Packaging
[CLP] Regulation.

Authorised Signatory :

Name : Steeve Lamvohee
Position : Regulatory Affairs Director
Signed : 
Dated : 14 - May - 2019

Certificate Reference : HU/119 issue 002

Product Code:

Code	Size
66800710	28 mL