

Smith & Nephew Medical Limited
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 : OPSITE Flexigrid

Classification : Class IIa

GMDN Code and Term : 58301 - Synthetic polymer semi-permeable film dressing, adhesive, 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
Body No. 2797 (British Standards Institute Netherlands)
British Standards Institute Netherlands. Certificate No. MD 76718
Quality Management System (BS EN ISO 13485)
British Standards Institute Netherlands. 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 13726-2:2002
BS EN 780:2015
BS EN 556-1:2001/AC:2006
BS EN ISO 11607-1:2009
BS EN ISO 11607-2:2006
BS EN ISO 10993-1:2009/AC:2010
BS EN ISO 10993-5:2009
BS EN ISO 10993-10:2013

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BS EN 15223-1:2016
BS EN ISO 11737-2:2009
BS EN ISO 11135:2014
BS EN 13726-3:2003
BS EN 1041:2008
BS EN ISO 14644-1:2015
BS EN 11737-1:2006/AC:2009
BS EN ISO 10993-7:2008/AC:2009
BS EN ISO 10993-18:2009

PRODUCT CODES

| Code | Size |
|----------|-------------|
| 66000376 | 6cm x 7cm |
| 4628 | 6cm x 7cm |
| 4629 | 10cm x 12cm |
| 4630 | 10cm x 12cm |
| 66004964 | 12cm x 12cm |
| 66004633 | 10cm x 8cm |
| 66030333 | 6cm x 7cm |
| 66320333 | 6cm x 7cm |
| 66030334 | 10cm x 12cm |
| 66320334 | 10cm x 12cm |
| 66000605 | 6cm x 7cm |
| 4631 | 15cm x 20cm |
| 4632 | 25cm x 12cm |

Authorised Signatory :**Name :**HELEN MAY**Position :**SNR REGULATORY AFFAIRS MANAGER**Signed :**Helen M. May**Dated :**20 - AUG - 2019**Certificate Reference**

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