

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 Smith & Nephew Medical Limited

Name :

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 Swab

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 Institution)

British Standards Institution. Certificate No. MD 76718 Quality Management System (BS EN ISO 13485)

British Standards Institution. Certificate No. FM 24676 Quality Management System (BS EN ISO 9001)

Standards Applied: BS EN 556-1:2001/AC:2006

BS EN ISO 1041: 2008

BS EN ISO 9001:2015

BS EN ISO 13485:2016

BS EN ISO 14971:2012

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 10993-18:2009

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 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

Product Codes:

Code	Size / Description
66800711	3 ml Secura No sting Barrier Film Swabs
66800787	3 ml Secura No sting Barrier Film Swabs
66800788	3 ml Secura No sting Barrier Film Swabs
66800789	1 ml Secura No sting Barrier Film Swabs

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66800790	1 ml Secura No sting Barrier Film Swabs
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Authorised Signatory:

Name:

Helen May

Position:

Sr Regulatory Affairs Manager

Signed:

Dated:

Helen M. May

18-MAR-2020

Certificate Reference:

HU/118 issue 003