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 and Nephew Medical Limited
Business Address:	101 Hessle Road, Hull HU3 2BN United Kingdom
Medical Devices:	IODOSORB / IODOFLEX Dressing
Classification:	Class III
GMDN Code and Term:	34083 – Biochemically Interactive dressing.
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. 0086 (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)
Design Examination Certificate:	CE 511078

Standards Applied:

BS EN ISO 13485: 2012	BS EN ISO 10993-5:2009
BS EN ISO 14971: 2012	BS EN ISO 556-1:2001/AC:2006
BS EN ISO 9001: 2008	BS EN ISO 10993-18: 2009
BS EN ISO 15223-1:2012	BS EN ISO 11137-2:2009
BS EN ISO 780:1999	BS EN ISO 11137-1:2006
BS EN 1041: 2008	BS EN ISO 11607-2:2006
BS EN ISO 10993-1:2009/AC:2010	BS EN ISO 14644 -1:1999
BS EN ISO 10993-2:2006	BS EN ISO 11607-1: 2009
BS EN ISO 10993:3-2009	ISO/TS 15843:2000
BS EN ISO 10993-10:2010	BS EN 980:2008

Authorised Signatory:

Name: Susan J McLoughlin,
Position: Regulatory Affairs Director

Signed: 

For and behalf of Smith and Nephew Medical Limited

Dated: 15/04/2016.
Certificate Reference: DC 009 issue 005