

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 of 14th June 1993 (as amended) concerning medical devices.

Manufacturer's Name :	Smith and 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 :	DURAFIBER Ag
Classification :	Class III Sterile
GMDN Code and Term :	47474 Exudate absorbent dressing, hydrophilic gel-forming, anti-microbial
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 including design examination. 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 00356 Full Quality Assurance British Standards Institution. Certificate No. MD 76718 Notified Body Number 2797 (British Standards Institution Netherlands) Quality Management System (BS EN ISO 13485) British Standards Institution. Certificate No. FM 24676 Quality Management System (BS EN ISO 9001) EC Design Examination Certificate (CE 568730)
Standards Applied :	BS EN ISO 13485:2016 BS EN ISO 14971:2012 BS EN ISO 9001:2015 BS EN 13726-1:2002/AC:2003 BS EN ISO 15223-1:2012 BS EN ISO 780:2015 BS EN 1041:2008 BS EN ISO 10993-1:Oct 2009/AC:2010 BS EN ISO 10993-2:2006

BS EN ISO 10993-3:2014
BS EN ISO 10993-5:2009
BS EN ISO 10993-10:2013
BS EN ISO 10993-18:2009
BS EN 556-1:2001/AC:2006
BS EN ISO 11137-1:2015
BS EN ISO 11137-2:2015
BS EN ISO 11607-1:2009
BS EN ISO 14644-1:2015

Product Codes:

Code	Size
66800578	5cm x 5cm
66800579	10cm x 10cm
66800580	15cm x 15cm
66800581	20cm x 30cm
66800582	2cm x 45cm
66800583	4cm x 10cm
66800584	4cm x 20cm
66800585	4cm x 30cm
66800034	5cm x 5cm
66800035	10cm x 10cm
66800036	15cm x 15cm
66800037	20cm x 30cm
66800038	2cm x 45cm

Authorised Signatory :
Name :

STEVE LAMVOHEE

Position :

RA DIRECTOR

Signed :



Dated :

04-SEP-2020

Certificate Reference :

DC 013 Issue 10