

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 : IV3000
IV3000 1-Hand

Classification :
GMDN Code and Term : Class I Sterile
Scope of Application : 34864 – Bandage, Adhesive

Declaration : All batches supplied to which the Declaration of Conformity Procedure has been applied. 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 14971:2012
BS EN ISO 11135:2014
BS EN ISO 9001:2015
BS EN ISO 11607-1:2009
BS EN ISO 11607-2:2009
BS EN 13726-2:2002
BS EN 13726-3:2003
BS EN ISO 780:2015
BS EN ISO 1041: 2008
BS EN 556-1:2001 /AC:2006
BS EN ISO 10993-1:2009 / AC:2010
BS EN ISO 10993-2:2006
BS EN ISO 10993-3:2014

BS EN ISO 10993-5:2009
BS EN ISO 10993-7:2008 / AC:2009
BS EN ISO 10993-10:2013
BS EN ISO 10993-12:2012
BS EN ISO 10993-18:2009
BS EN ISO 14644-1:2015
BS EN ISO 13485:2016
EN ISO 15223-1:2016

Authorised Signatory :

Name :

STEVE LAMMOHEE

Position :

PA DIRECTOR

Signed :



Dated :

19-SEP-2019

Certificate Reference :

HU/004 issue 32

Product Codes:

IV3000

Code	Size
4923	6cm x 8cm
4924	6cm x 8.5cm
66024007	6cm x 7cm
66024008	10cm x 12cm

Products manufactured at S&N Medical (Suzhou) Ltd, China

Code	Size
4925	10cm x 14cm
4973	10cm x 14cm
4649	10cm x 20cm

IV3000 1-Hand

Code	Size
4007	6cm x 7cm
4008	10cm x 12cm
66004005	10cm x 12cm
4654	5cm x 4cm
4006	7cm x 9cm
66004009	9cm x 12cm
66004011	5cm x 6cm
66800512	11cm x 14cm

Products manufactured at S&N Medical (Suzhou) Ltd, China

Code	Size
4006	7cm x 9cm
4007	6cm x 7cm
4008	10cm x 12cm