

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 : Leukostrip

Classification : Class IIa Sterile
GMDN Code and Term : 34864 – Bandage, Adhesive
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. 2797 (British Standards Institute)

Standards Applied : 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)

BS EN ISO 9001:2015

BS EN ISO 13485:2016

BS EN ISO 14971:2012

BS EN 556-1:2001/AC:2006

BS EN ISO 780:2015

BS EN ISO 15223-1:2012

BS EN 980: 2008

BS EN ISO 10993-1:2009/AC:2010

BS EN ISO 10993-5:2009

BS EN ISO 10993-2:2006

BS EN ISO 10993-3:2014

BS EN ISO 10993-10:2013

BS EN ISO 10993-12:2012
 BS EN ISO 10993-18:2009
 BS EN ISO 11137-1:2015
 BS EN ISO 11137-2:2015
 BS EN ISO 14644 -1:1999/AC: 2001
 BS EN ISO 11607-1: 2009
 BS EN ISO 11607-2:2006
 BS EN ISO 1041: 2008
 BS EN 13726-1:2002/AC:2003
 BS EN 13726-2: 2002

Authorised Signatory :

Name :

STEEVE LAMMOUÉE

Position :

RA DIRECTOR

Signed :



Dated :

16-APR-2019

Certificate Reference :

HU/024 issue 15

PRODUCT CODES:

Code	Size
LEUKOSTRIP	
66002879	6.4mm x 102mm Dressings
66002881	26mm x 102mm Dressings
66002880	13mm x 102mm Dressings
66002876	4mm x 38mm Dressings
66072954	4mm x 38mm Dressings
66002878	6.4mm x 76mm Dressings
66002903	4mm x 76mm Dressings
66002952	6.4mm x 76mm Dressings
66072955	6.4mm x 102mm Dressings
66002953	13mm x 102mm Dressings
LEUKOSTRIP S	
66002882	4mm x 38mm Dressings
66102872	4mm x 38mm Dressings 6.4mm x 76mm Dressings
66002883	6.4mm x 76mm Dressings