

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 :

CUTIPLAST Steril/CUTIPLAST Plus Steril

Classification :

Class I 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 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

Verification Certificate(s):

Documentation.

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 9001:2015
BS EN ISO 13485:2016
BS EN ISO 14971:2012
BS EN 556-1:2000/AC:2006
BS EN ISO 11137-1:2006
BS EN ISO 11137-2:2018
BS EN ISO 14644-1:2015
BS EN ISO 11607-1:2009
BS EN ISO 1041:2008
BS EN ISO 780:2015
BS EN ISO 10993-1:2009/AC:2010
BS EN 13726-1:2002/AC:2003
BS EN 13726-2:2002
BS EN 13726-3:2003
BS EN 13726-4:2003
BS EN ISO 15223-1:2016

Authorised Signatory :

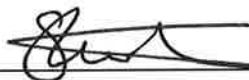
Name :

STEVE LAMMOUE

Position :

RA DIRECTOR

Signed :



Dated :

29-MAR-2019

Certificate Reference :

HU/010 issue 16

PRODUCT CODES:

Code	Size
CUTIPLAST Steril	
66001473	10cm x 8cm Dressing
66001474	15cm x 8cm Dressing
66001475	20cm x 10cm Dressing
66001476	25cm x 10cm Dressing
66001477	30cm x 10cm Dressing
66001478	7.2 x 5cm Dressing
66076825	7.2cm x 5cm Dressing
66076826	10cm x 8cm Dressing
66076832	20cm x 10cm Dressing
66076833	25cm x 10cm Dressing
66176825	7.2cm x 5cm Dressing
66176826	10cm x 8cm Dressing
66176827	15cm x 8cm Dressing
CUTIPLAST Plus Steril	
66801160	7cm x 5cm
66801161	10cm x 7.8cm
66801162	15cm x 7.8cm
66801163	19.8cm x 10cm
66801164	24.8cm x 10cm
66801165	29.8cm x 10cm
66801166	7cm x 5cm
66801167	10cm x 7.8cm
66801599	15cm x 7.8cm
66801600	19.8cm x 10cm
66801601	24.8cm x 10cm