

## 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 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 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 :**

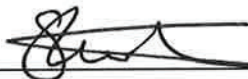
**Name :**

STEEVE LAMMOLEE

**Position :**

RA DIRECTOR

**Signed :**



**Dated :**

29-MAR-2019

**Certificate Reference :**

HU/010 issue 16

**PRODUCT CODES:**

Code	Size
<b>CUTIPLAST Steril</b>	
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
<b>CUTIPLAST Plus Steril</b>	
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