

## 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 :** Applica IV 100

**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)

**Standards Applied :** 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 11137-1:2006  
BS EN ISO 11137-2:2013  
BS EN ISO 14644-1:2015  
BS EN ISO 11607-1:2009+A1:2014  
BS EN 13726-2:2002  
BS EN ISO 780:2015  
BS EN ISO 1041: 2008  
BS EN ISO 10993-1:October 2009  
BS EN ISO 10993-18:2009  
BS EN ISO 15223-1:2016

Smith & Nephew Medical Ltd.  
101 Hessle Road  
Hull, HU3 2BN  
England

T + 44 (0) 1482 225181  
F + 44 (0) 1482 328326  
www.smith-nephew.com



**Authorised Signatory :**

**Name :**

STEEVE LAMLOUPE

**Position :**

RA DIRECTOR

**Signed :**



**Dated :**

16-APR-2019

**Certificate Reference :**

HU/018 issue 10

**PRODUCT CODES**

Code	Size
66047717	8cm x 6cm dressing