

Wound Management  
Smith & Nephew  
Medical Ltd  
101 Hessle Road  
Hull HU3 2BN  
England

T 44 (0) 1482 225 181  
F 44 (0) 1482 328 326  
www.smith-nephew.com



## 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 and Nephew Medical Limited

**Business Address :** 101 Hessle Road,  
Hull  
HU3 2BN  
United Kingdom

**Medical Devices :** ACTICOAT

**Classification :** Class III

**GMDN Code and Term :** 47042, Wound non-adherent dressing, absorbent, antimicrobial

**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. 0086 (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)

**Design Examination Certificate :**  
**Standards Applied :**

|                                  |                           |
|----------------------------------|---------------------------|
| CE 90692                         |                           |
| BS EN ISO 13485: 2012            | BS EN ISO 15223-1:2012    |
| BS EN ISO 780:1999               | BS EN 980:2008            |
| BS EN ISO 10993-3:2014           | BS EN ISO 10993-5:2009    |
| BS EN ISO 10993-18: 2009         | BS EN 556-1:2001/AC:2006  |
| BS EN ISO 11137-1:2006 +A1 2013  | BS EN ISO 11137-2:2015    |
| BS EN ISO 11607-1: 2009 +A1 2014 | BS EN ISO 14971: 2012     |
| BS EN ISO 14644 -1:1999/AC: 2001 | BS EN ISO 9001: 2008      |
| BS EN 13726-1:2002/AC:2003       | BS EN 13726-2:2002        |
| BS EN 13726-4:2003               | BS EN 1041: 2008 +A1 2013 |
| BS EN 13726-3: 2003              | BS EN ISO 10993-2:2006    |
| BS EN ISO 10993-1:2009           | BS EN ISO 10993-10:2013   |

**Authorised Signatory :**

**Name :** Susan McLoughlin  
**Position :** Director, Regulatory Affairs

**Signed :**

**Dated :**

10/12/2015

**Certificate Reference**

DD 006 issue 09