

## 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,

**Medical Devices :**

Germany

**Classification :**

ALGISITE M

**GMDN Code and Term :**

Class IIb Sterile

**Scope of Application :**

43186 – Exudate-absorbent dressing, hydrophilic-gel, sterile  
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

**Verification Certificate(s):**

accordance with the information set out in the dossier.  
EC Certificate No. CE 00356 Full 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 556-1:2001/AC:2006  
BS EN ISO 13485:2016                    BS EN ISO 14971:2012  
BS EN ISO 10993-1:2009                BS EN ISO 11137-1:2015  
BS EN ISO 10993-5:2009                BS EN ISO 11137-2:2015  
BS EN ISO 10993-10:2013                BS EN 13726-1:2002 /AC: 2003  
BS EN ISO 15223-1:2016                BS EN ISO 14644-1:2015  
BS EN ISO 780:2015                      BS EN ISO 11737-1:2006 / AC:2009  
BS EN 1041:2008+A1:2013

**Authorised Signatory :**

**Name :**

STEVE LAMVORRE

**Position :**

RA DIRECTOR

**Signed :**



**Dated :**

29-MAR-2019

**Certificate Reference :**

HU/029 issue 013

### PRODUCT CODES

Code	Size
66000519	5cm x 5cm dressing
66000520	10cm x 10cm dressing
66000521	15cm x 20cm dressing
66000522	2cm x 30cm dressing
66000718	10cm x 10cm dressing
66000719	15cm x 15cm dressing

