

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
accordance with the information set out in the dossier.

Verification Certificate(s):

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

