

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 : ALLEVYN Adhesive

Classification : Class IIb Sterile
GMDN Code and Term : 44970 exudate-absorbent dressing, non-gel
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. 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 :

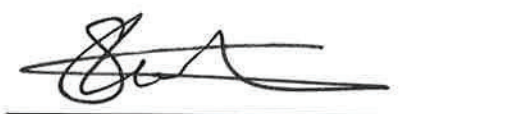
- BS EN ISO 13485:2016
- BS EN ISO 9001:2015
- BS EN ISO 14971:2012
- BS EN 556-:2001/AC:2006
- BS EN ISO 11137-1:2015
- BS EN ISO 11137-2:2015
- BS EN ISO 14644-1:2015
- BS EN ISO 11607-1: 2009
- BS EN ISO 780:2015
- BS EN ISO 1041:2008
- BS EN ISO 10993-1:2009/AC:2010
- BS EN ISO 10993-2:2006
- BS EN ISO 10993-3:2014
- BS EN ISO 10993-5:2009
- BS EN ISO 10993-10:2013
- BS EN ISO 10993-12:2012
- BS EN ISO 10993-18:2009

BS EN 13726 Part 1: 2002/AC:2003
BS EN 13726 Part 2: 2002
BS EN 13726 Part 3: 2003
BS EN 13726 Part 4: 2003
BS EN ISO 15223:2012

Authorised Signatory :

Name : STEELE LAMVOREE
Position : RA DIRECTOR

Signed



Dated :

19- SEP - 2019

Certificate Reference

HU/005 issue 39

PRODUCT CODES

Product codes manufactured at Suzhou, China

Code	Size
66000700	17cm x 17cm Sacrum dressing
66012593	17cm x 17cm Sacrum dressing
66800016	17cm x 17cm Sacrum dressing
66000043	7.5cm x 7.5cm dressing
66800009	7.5cm x 7.5cm dressing
66000044	12.5cm x 12.5cm dressing
66800010	12.5cm x 12.5cm dressing
66000045	17.5cm x 17.5cm dressing
66800011	17.5cm x 17.5cm dressing
66000597	12.5cm x 12.5cm dressing
66000694	17cm x 17cm Sacrum dressing
66320700	17cm x 17cm Sacrum dressing
66000451	22cm x 22cm Sacrum dressing
66000777	15cm x 15cm dressing
66000046	22.5cm x 22.5cm dressing
66800012	22.5cm x 22.5cm dressing
66000744	12.5cm x 22.5cm dressing
66000599	10cm x 10cm dressing
66150043	7.5cm x 7.5cm dressing
66150046	22.5cm x 22.5cm dressing
66000348	7.5cm x 7.5cm dressing
66150045	17.5cm x 17.5cm dressing

66150044	12.5cm x 12.5cm dressing
66000349	12.5cm x 12.5cm dressing
36361422	7.5cm x 7.5cm dressing
66801111	7cm x 8cm
66801112	12cm x 13cm
66801113	13cm x 22cm
66801114	17cm x 18cm
66801115	22cm x 23cm
66801140	7cm x 8cm
66801141	12cm x 13cm
66801142	13cm x 22cm
66801143	17cm x 18cm
66801144	22cm x 23cm
66801111s	7cm x 8cm

Product codes manufactured at the Hull site

Code	Size
66150043	7.5cm x 7.5cm dressing
66150046	22.5cm x 22.5cm dressing
66000348	7.5cm x 7.5cm dressing
66150045	17.5cm x 17.5cm dressing
66000599	10cm x 10cm dressing
66150044	12.5cm x 12.5cm dressing
66000349	12.5cm x 12.5cm dressing
66000043	7.5cm x 7.5cm
66000044	12.5cm x 12.5cm
66000045	17.5cm x 17.5cm
66000046	22.5cm x 22.5cm
66000700	17cm x 17cm Sacrum dressing
66000451	22cm x 22cm Sacrum dressing