


## 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).

<b>Manufacturer's Name:</b>	Smith & Nephew Medical Limited
<b>Business Address:</b>	101 Hessle Road, Hull, HU3 2BN, United Kingdom
<b>Authorised Representative:</b>	Smith & Nephew Orthopaedics GmbH, Alemannenstraße 14, 78532 Tuttlingen, Germany
<b>Medical Devices:</b>	CUTICERIN
<b>Classification:</b>	Class IIa
<b>GMDN Code and Term:</b>	46855 Wound-non adherent dressing, permeable
<b>Scope of Application:</b>	All batches supplied to which the Declaration of Conformity Procedure has been applied.
<b>Declaration:</b>	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.
<b>Verification Certificate(s):</b>	EC Certificate No. CE 00356 Full Quality Assurance. Notified Body No. 2797 (British Standards Institution) British Standards Institution. Certificate No. MD 76718 Quality Management System (BS EN ISO 13485) British Standards Institution. Certificate No. FM 24676 Quality Management System (BS EN ISO 9001)
<b>Standards Applied:</b>	BS EN ISO 9001:2015 BS EN ISO 13485:2016 BS EN ISO 14971:2019 BS EN 556-1:2001/AC:2006 BS EN ISO 11137-2:2015 BS EN ISO 780:2015 BS EN 1041:2008 BS EN ISO 10993-1:2018 BS EN ISO 10993-5:2009 BS EN ISO 10993-10:2013 BS EN ISO 10993-18:2009 BS EN ISO 15223-1:2016 BS EN ISO 11607-1:2009+A1:2014 BS EN ISO 11737-1:2018

		BS EN ISO 14644-1:2015	
<b>Product Codes:</b>	<b>Code</b>	<b>Size and Description</b>	
	66045562	7.5cm x 7.5cm dressing	
	66045560	7.5cm x 7.5cm dressing	
	66045563	7.5cm x 20cm dressing	
	66045561	7.5cm x 20cm dressing	
	66045502	20cm x 40cm dressing	
	66045564	10cm x 10cm dressing	
	66045503	7.5cm x 20cm dressing	

<b>Authorised Signatory:</b>	
<b>Name:</b>	Ken Fergusson
<b>Position:</b>	Senior Regulatory Affairs Manager
<b>Signed:</b>	
<b>Dated:</b>	11 August 2021
<b>Certificate Reference:</b>	HU/030 issue 10