

Smith & Nephew Medical Ltd.
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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:	Leukostrip
Classification:	Class IIa Sterile
GMDN Code and Term:	34864 – Bandage, Adhesive
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 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)
Standards Applied:	BS EN ISO 9001:2015 BS EN ISO 13485:2016

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	BS EN ISO 14971:2012 BS EN 556-1:2001/AC:2006 BS EN ISO 780:2015 BS EN ISO 15223-1: 2016 BS EN ISO 10993-1: 2018 BS EN ISO 10993-5:2009 BS EN ISO 10993-2:2006 BS EN ISO 10993-3:2014 BS EN ISO 10993-10:2013 BS EN ISO 10993-12:2012 BS EN ISO 10993-18: 2020 BS EN ISO 11137-1:2015 BS EN ISO 11137-2:2015 BS EN ISO 14644 -1: 2015 BS EN ISO 11607-1: 2017 BS EN ISO 11607-2: 2020 BS EN ISO 20417:2021 BS EN 13726-1:2002 BS EN 13726-2:2002			
Product Codes:	Code	Size	Code	Size
	Leukostrip			
	66002879	6.4mm x 102mm	66002881	26mm x 102mm
	66002880	13mm x 102mm	66002876	4mm x 38mm
	66072954	4mm x 38mm	66002878	6.4mm x 76mm
	66002903	4mm x 76mm	66002952	6.4mm x 76mm
	66072955	6.4mm x 102mm	66002953	13mm x 102mm
	Leukostrip S			
	66002882	4mm x 38mm	66102872	4mm x 38mm & 6.4mm x 76mm
	66002883	6.4mm x 76mm		

Authorised Signatory:	
Name:	Sam Greenhalgh
Position:	Senior Regulatory Manager
Signed:	DocuSigned by:  Signer Name: Sam Greenhalgh Signing Reason: I approve this document Signing Time: 29-Nov-2022 16:09:48 GMT
Dated:	29-Nov-2022 16:09:48 GMT
Certificate Reference:	HU/024 issue 16