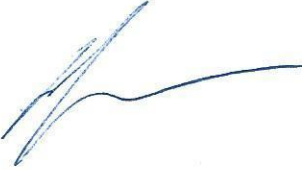


## EUROPEAN DECLARATION OF CONFORMITY

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>	Proshield Plus
<b>Classification:</b>	Class IIa
<b>GMDN Code and Term:</b>	46206 – Skin moisture barrier dressing
<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 56481 Production Quality Assurance. Notified Body No. 2797 (British Standards Institution) European conformity assessed in accordance with Annex V and VII of the Directive 93/42/EEC on Medical Devices (Class IIa) 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 ISO 780:2015 BS EN ISO 20417:2021 BS EN ISO 10993-1: 2018 BS EN ISO 10993-3:2014 BS EN ISO 10993-5:2009 BS EN ISO 10993-10:2013 BS EN ISO 10993-11:2009 BS EN ISO 10993-17:2017 BS EN ISO 10993-18: 2020 BS EN ISO 15223-1:2021		
Product Codes:	Code	Size	Carton Quantity
	8213-0300-04	115g	1 tube with IFU and 12 cartons per case

Authorised Signatory:	
Name:	Ken Fergusson
Position:	Senior Regulatory Affairs Manager
Signed:	
Dated:	25 MAY 2022
Certificate Reference:	HU/165 issue 002