

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:	Proshield Plus
Classification:	Class IIa
GMDN Code and Term:	46206 – Skin moisture barrier dressing
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 V and Annex VII of the Directive. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier Technical Documentation.
Verification Certificate(s):	EC Certificate No. CE 56481 Production 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 BS EN ISO 14971:2012 BS EN ISO 780:2015 BS EN 1041:2008 +A1:2013 BS EN ISO 10993-1: 2018 BS EN ISO 10993-5:2009 BS EN ISO 10993-10:2013

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BS EN ISO 10993-11:2009
BS EN ISO 10993-17:2009
BS EN ISO 10993-18:2009
BS EN ISO 15223-1:2016

Product Codes:

Code	Size	Carton Quantity
8213-0300-04	115g	1 tube with IFU and 12 cartons per case

Authorised Signatory:

Name:

Steeve Lamvohee

Position:

Regulatory Affairs Director

Signed:

A handwritten signature in black ink, appearing to read "Steeve", written over a horizontal line.

Dated:

02 - MAR - 2021

Certificate Reference:

HU/165 issue 001