

Smith & Nephew Medical Ltd.
101 Hessle Road
Hull, HU3 2BN
England

T + 44 (0) 1482 225181
F + 44 (0) 1482 328326
www.smith-nephew.com



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 Foam & Spray
Classification: Class IIa

GMDN Code and Term: 46205 – Excretion/excreta skin cleanser

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 VI of the Directive. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier of 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 10993-10:2013

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BS EN ISO 10993-3:2014
BS EN ISO 10993-17:2009
BS EN ISO 15223-1:2016

Product Codes:

Code	Size	Carton Quantity
8213-0150-08	235ml	1 bottle and 12 bottles per case

Authorised Signatory:

Name:

Helen May

Position:

Senior Regulatory Affairs Manager

Signed:

Helen M. May

Dated:

23-DEC-2020

Certificate Reference:

HU/164 issue 001