Smith & Nephew, Inc.
5600 Clearfork Main St., Ste. 600
Fort Worth, TX 76109
USA

817-900-4000
800-441-8227
www.smith-nephew.com

European Declaration of Conformity

smith&nephew

PRODUCT IDENTIFICATION	
Product name	**Model/number**
PROSHIELD® Plus Skin Protectant	Product Code 8213-0300-04

MANUFACTURER		
Name of company	**Business Address**	**Quality Representative**
Smith & Nephew, Inc.	5600 Clearfork Main Street, Suite 600 Fort Worth, Texas 76109, USA	Blake Hemmel, Quality Director

AUTHORIZED REPRESENTATIVE		
Name of company	**Address**	**Telephone/eMail**
Smith & Nephew Orthopaedics GmbH	Alemannenstraße 14, Tuttlingen, Baden Württemberg, Germany 78532	+49 7462 208 144 rainer.brunnen@smith-nephew.com

CONFORMITY ASSESSMENT			
Device Classification	**GMDN Code and Term**	**Route to compliance**	**Standards applied**
Class 1 Non-sterile Rule 4	46206 Skin moisture barrier dressing	Annex VII of MDD 93/42/EEC Council Directive	BS EN 980:2008 BS EN 1041:2008 BS EN ISO 780:2015 BS EN ISO 10993-1:2009 BS EN ISO 10993-10:2013 BS EN ISO 14971:2012

Smith & Nephew, Inc. declares that the above mentioned product meets the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Amy Campbell, RAC

TITLE: Regulatory Affairs Director

SIGNATURE: Amy Campbell

DATE (DD/MMM/YYYY): 19 Mar 2019