

## Declaration of Conformity

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

MANUFACTURER		
Name of company	Address	Quality Representative
Smith & Nephew, Inc.	3909 Hulen Street Fort Worth, Texas 76107, USA	Blake Hemmel, Quality Director

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/eMail
Smith & Nephew Medical Limited	101 Hessle Road Kingston-upon-Hull HU3 2BN, United Kingdom	+44 (0) 1482 673790 <a href="mailto:samantha.neilson@smith-nephew.com">samantha.neilson@smith-nephew.com</a>

CONFORMITY ASSESSMENT		
Device Classification	Route to compliance	Standards applied
Class 1 Rule 4	Annex VII of MDD 93/42/EEC Council Directive	EN 980:2008 EN 1041:2008 EN ISO 14971:2007

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:** Bobbi Drais MS, RAC

**TITLE:** Vice President, Regulatory Affairs

**SIGNATURE:** 

**DATE (DD/MM/YYYY):** 01/12/2015