

## 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 :** OPSITE Spray  
**Classification :** Class IIa  
**GMDN Code and Term :** 58978 – Synthetic- polymer liquid barrier dressing, non-sterile  
**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 of Technical Documentation.

**Verification Certificate(s):** EC Certificate No. CE 56481 Production Quality Assurance.  
Notified Body No. 2797 (British Standards Institute)  
British Standards Institute. Certificate No. MD 76718 Quality Management System (BS EN ISO 13485)  
British Standards Institute. Certificate No. FM 24676 Quality Management System (BS EN ISO 9001)

**Standards Applied :**

BS EN ISO 14971:2012	BS EN 1041:2008+A1:2013
BS EN ISO 9001:2015	BS EN ISO 10993 - 1:2018
BS EN ISO 13485:2016	BS EN ISO 10993 - 10:2013
BS EN ISO 780:2015	BS EN ISO 10993-3:2014
BS EN 13726-2:2002	BS EN ISO 15223-1:2016
Regulation (EC) No 1272/2008	BS EN ISO 14644-1:2015
Council directive 80/232/EEC	
Aerosol directive 75/324/EEC and amendment 94/1/EC	

**Authorised Signatory :**

**Name :**

DARREN J. THAIN

**Position :**

Sr. RA Manager

**Signed :**

**Dated :**

[Signature]  
18<sup>th</sup> September 2020.

**Certificate Reference :**

HU/040 issue 011

### PRODUCT CODES

Code	Size
66004978	100ml
66004979	100ml
66004980	240ml
66800653	240ml
Consumer Select	
66000679	40ml