

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: VERSAJET II Hydrosurgery Handpiece

Classification: Class IIa Sterile

GMDN Code and Term: 47559: Water jet knife system handpiece, single-use

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 II of the Directive. A dossier of technical documentation, as required by the Directive is available. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier.

Verification Certificate(s): EC Certificate No. CE 00356 Full 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 556-1:2001/AC:2006	BS EN ISO 11135-1:2014
BS EN ISO 780:2015	BS EN ISO 11607-1: 2009
BS EN 1041: 2008	BS EN ISO 11607-2:2006
BS EN ISO 9001:2015	BS EN ISO 11737-1:2006/AC:2009
BS EN ISO 10993-1:2009/AC:2010	BS EN ISO 11737-2:2009
BS EN ISO 10993-5:2009	BS EN ISO 13485:2016
BS EN ISO 10993-7:2008/AC:2009	BS EN ISO 14644 -1:2015
BS EN ISO 10993-10:2013	BS EN ISO 14971:2019
BS EN ISO 10993-12:2012	BS EN ISO 15223-1:2016
BS EN ISO 10993-18:2009	Restriction of Hazardous Substances
ISTA 2A: 2011	(RoHS) Directive – 2011/65/EU

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Smith+Nephew

Authorised Signatory

Name : KEN FERLUSON
Position : SENIOR REGULATORY AFFAIRS MANAGER
Signed : 
Dated : 29 JAN 2021
Certificate Reference HU/138 Issue 6

Product Codes:

Code	Size
66800040	EXACT Disposable Handpiece, 15° 14mm
66800041	EXACT Disposable Handpiece, 45° 14mm
66800042	EXACT Disposable Handpiece, 45° 8mm
66800043	PLUS Disposable Handpiece, 15° 14mm
66800044	PLUS Disposable Handpiece, 45° 14mm
66800045	PLUS Disposable Handpiece, 45° 8mm