

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 Console & Footswitch
Classification:	Class IIb Non-Sterile
GMDN Code and Term:	36961: Water jet knife system generator
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 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 780:2015 BS EN 1041: 2008 BS EN ISO 9001:2015 BS EN ISO 13485:2016 BS EN ISO 14971:2019 BS EN ISO 15223-1:2016 IEC 60601-1:2005 +AMD1:2012 3.1 Edition IEC 60601-1-2:2014 4 th Edition IEC 60601-1-6:2010 3 rd Edition

England

	IEC 62366:2007 BS EN 62304:2006+A1:2015 (IEC 62304:2006) BS EN 50581:2012 IEC/ EN 62321:2009 Restriction of Hazardous Substances (RoHS) Directive – 2011/65/EU ISTA 2A: 2011	
Product Codes:	Code	Size
	66800039	15in W x 11.8in D x 5.8in H / 38.1cm W x 30cm D x 14.8cm H
	66800472	7.5in W x 7.25in D x 2in H / 19cm W x 18.4cm D x 5cm H
	66800474	N/A

Authorised Signatory:	
Name:	<u>KEN FERCUSSON</u>
Position:	<u>SENIOR REGULATORY AFFAIRS MANAGER</u>
Signed:	
Dated:	<u>29 JAN 2024</u>
Certificate Reference:	HU/137 issue 08