	TECHNICAL FILE – DECLARATION OF CONFORMITY
DESCRIPTION	Intelect Radial Pressure Wave and Accessories
CLASSIFICATION	IIa

Revision	Effective Date	Originator	Description
A	October 19, 2016	L. Brookfield	Initial Release into new DOC template
B	May 22, 2018	Sali Gully	Update on revision number for product's PN list and CER standard revision number
C	See Agile	L Mullens	QMS-08389 Update EC Certificate number to BSI
D	See Agile	T. Allard	QMS-10244 Update EC Certificate expiry and standards list

DECLARATION OF CONFORMITY		
MANUFACTURER	DJO FRANCE SAS Centre Européen de Frêt, 3 rue de Bethar, 64990 Mouguerre, France	
PRODUCT	Intelect RPW System	
PART NUMBER LIST	Refer to TF-FRA-004-3 Intelect RPW System Part Number List Rev C	
MDD CLASSIFICATION	Class IIa	
CONFORMITY ASSESSMENT ROUTE	Annex II (EC Declaration of Conformity)	
GMDN CODE	47032	
UMDNS CODE	N/A	
WE, THE MANUFACTURER, DJO FRANCE SAS, DECLARE UNDER SOLE RESPONSIBILITY THAT THE ITEM TO WHICH THIS DECLARATION IS RELATED IS IN CONFORMITY WITH: • ALL RELEVANT PROVISIONS OUTLINED IN THE OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITY COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES. THE ITEM COMPLIES WITH ALL RELEVANT PROVISIONS OF THE ANNEX I ESSENTIAL REQUIREMENTS, AS AMENDED UP TO AND INCLUSIVE OF COUNCIL DIRECTIVE 2007/47/EC. • DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 8 JUNE 2011 ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (ROHS-2)		
STANDARDS APPLIED	EN ISO 13485:2016/AC:2016	Medical Devices – Quality management system – Requirements for regulatory purposes
	EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
	EN 1041:2008	Information supplied by the manufacturer with medical devices
	EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	ISO 15223-2:2010	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 2: Symbol development, selection and validation
	ISO 10993-1:2009/AC:2010	Biological Evaluation of medical devices – Part 1: General requirements for basic safety and essential performance
	IEC 62366:2014	Medical devices – Application of usability
	IEC 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
	EN 60601-1-6:2010	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
NOTIFIED BODY (MDD)	BSI Group Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP Telephone: +44 (0) 1908 814844 Fax: +44 (0) 1908 814924 N/O No: 0086	
EC CERTIFICATE(S)	EC Certificate #: CE 681250 Issue date: 2018-07-27 Expiration date: 2024-01-23	

PLACE OF ISSUE	Mouguerre France
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO FRANCE SAS,  Name: Tim Allard Title: Senior Manager Regulatory (Affairs and Compliance) Date: January 30, 2019