TECHNICAL FILE – DECLARATION OF CONFORMITY

DESCRIPTION	Intelect Radial Pressure Wave 2 / RPW 2 and Accessories
CLASSIFICATION	IIa

Rev.	QMS Change	Originator	DESCRIPTION OF CHANGE	Release Date
A	QMS-13825	B. DOMBOVÁRI	Initial Release	28 JAN 2020
B	QMS-14337	S.POUY	Chattanooga brand name addition	SEE AGILE

DECLARATION OF CONFORMITY

MANUFACTURER	DJO FRANCE SAS Centre Européen de Frêt, 3 rue de Bethar, 64990 Mouguerre, France
PRODUCT	Chattanooga® Intelect RPW 2 System
PART NUMBER LIST	Refer to TF-FRA-015-3 Intelect RPW System Part Number List
MDD CLASSIFICATION **RED CLASSIFICATION**	Class IIa Class I
CONFORMITY ASSESSMENT ROUTE	Annex II (EC Declaration of Conformity; MDD) Annex II (RED)
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)
- DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 16 APRIL 2014 ON THE HARMONISATION OF THE LAWS OF THE MEMBER STATES RELATING TO THE MAKING AVAILABLE ON THE MARKET OF RADIO EQUIPMENT AND REPEALING DIRECTIVE 1999/5/EC

STANDARDS APPLIED	**EN ISO 13485:2016/AC:2016**	Medical devices - Quality management systems - Requirements for regulatory purposes
	IEC 60601-1:2005/A1:2012 EN 60601-1:2006/A1:2013	Safety Requirements for Medical Electrical Systems. Ed. 3.1
	IEC 60601-1-2:2014 EN 60601-1-2:2015	Electromagnetic Compatibility – Requirements and Tests. Ed. 3
	EN 60601-1-6:2010/A1:2013 IEC 60601-1-6:2010/AMD1:2013	Medical electrical equipment - General requirements for basic safety and essential performance - Collateral standard: Usability
	IEC 62366:2007/AMD1:2014 EN 62366-1:2016	Medical devices – Application of Usability
	IEC 62304:2006/AMD1:2015 EN 62304/A1:2015	Medical device software – Software life-cycle processes
	EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
	ISO 10993-1:2018	Biological Evaluation of medical devices – Part 1: General requirements for basic safety and essential performance
	ASTM D4169-16	Standard practice for performing testing of shipping containers and systems
	MEDDEV 2.7/1 rev.4	Clinical evaluation: Guide for manufacturers and notified bodies
	ETSI EN 301 489-1 V1.8.1 (2008-04)	Electromagnetic compatibility and Radio Spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
	ETSI EN 301 489-3 V1.4.1 (2002-08)	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz
	2014/53/EU	Radio Equipment Directive (RED)
	(EU) 207/2012	Electronic instructions for use of medical devices

NOTIFIED BODY (MDD)	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands 2797
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: Britta Dombovári Title: Regulatory Affairs Manager Date: 16 March 2020