	TECHNICAL FILE – DECLARATION OF CONFORMITY
DESCRIPTION	Intelect Mobile 2
CLASSIFICATION	IIa

Revision	Effective Date	Originator	Description
A	31 oct 2019	Dombovari, B.	Initial Release
B	18 nov 2019	Allard, T.	Add Ultrasound applicators codes Add ISO13485 to the standards table
C	See Agile	Pouy, S.	GMDN code update Addition of - GMDN 61186 for COMBO device, which is a multi-modality physical therapy system - GMDN 11248 for Ultrasound device - GMDN 63505 for ultrasound system handpiece
D	See Agile	Dombovári, B.	Remove UMDNS code 18823

DECLARATION OF CONFORMITY

MANUFACTURER	**DJO FRANCE SAS** 3 rue de Bethar Centre Européen de Frêt 64990 Mouguerre FRANCE
EU AUTHORIZED REPRESENTATIVE (MDD)	N/A
PRODUCT	Intelect Mobile 2
PART NUMBER LIST	TF-FRA-014-3
MDD CLASSIFICATION **RED CLASSIFICATION**	Class IIa Class 1
CONFORMITY ASSESSMENT ROUTE	Annex VII (MDD) Annex II (RED)
GMDN CODE	46573, 63505, 61186, 11248
UMDNS CODE	17908

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:2016ISO	Medical devices - Quality management systems - Requirements for regulatory purposes
	EN 60601-1:2006/A1:2013 IEC 60601-1:2005/A1:2012	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
	IEC 60601-2-5:2009 EN 60601-2-5:2015	Medical electrical equipment – Particular requirements for the safety of ultrasonic physiotherapy equipment. Ed. 3
	IEC 60601-2-10:2012/AMD1:2016 EN 60601-2-10:2016/A1:2016	Medical electrical equipment – Particular requirements for the basic safety and essential performance of nerve and muscle stimulators. Ed. 2
	IEC 60601-1-11:2015 EN 60601-1-11:2015	Medical electrical equipment —General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
	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 62366-1:2015 EN 62366-1:2016 IEC 62366 :2014	Medical devices – Application of Usability
	IEC 62133-1: 2017 (Nickel Systems) IEC 62133: 2012(Lithium Systems)	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
	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	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands 2797	
EC CERTIFICATE(S)	CE 681250	
PLACE OF ISSUE	64990 Mouguerre, France	
SIGNATURE	SIGNED FOR AND ON BEHALF OF **DJO FRANCE SAS**  Name: Britta Dombovári Title: Regulatory Affairs Manager Date: April 20, 2020	