TECHNICAL FILE – DECLARATION OF CONFORMITY	
DESCRIPTION	Intelect HPL7 and HPL15 Laser System
CLASSIFICATION	Class IIb

Revision	Effective Date	Originator	Description
A	September 19, 2016	L. Brookfield	Initial Release
B	September 27, 2016	L. Brookfield	Minor editorial changes
C	January 24, 2018	N. Li	Update EC Certificate revision number
D	August 21, 2018	L Mullens	QMS-08389 Update EC Certificate number to BSI
E	February 04, 2019	T. Allard	QMS-10244 Update EC Certificate expiry and standards list
F	August 08, 2019	K. Lakshmi	QMS- 12320 Update Notified Body Information
G	See Agile	T. Allard B. Dombovári	Update of Standards list and NB information Update of CE Certificate Issue Date

DECLARATION OF CONFORMITY	
MANUFACTURER	DJO FRANCE SAS Centre Européen de Frêt 3 rue de Bethar, 64990 Mouguerre France
EU AUTHORIZED REPRESENTATIVE (MDD)	N/A
PRODUCT	Intelect HPL7 and HPL15 High-Power Laser System.
PART NUMBER LIST	TF-FRA-012-3 Intelect HPL7 and HPL15 Laser System-Part Number List
MDD CLASSIFICATION RED CLASSIFICATION	Class IIb N/A
CONFORMITY ASSESSMENT ROUTE	Annex II Full Quality Assurance
GMDN CODE	60409
UMDNS CODE	12-299

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 14971:2019	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	BSI Group Say Building, John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 780 NB No: 2797	
EC CERTIFICATE(S)	EC Certificate #: CE 681250 Issue date: 2020-09-22 Expiration date: 2024-01-23	

PLACE OF ISSUE	Mouguerre, France
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO FRANCE SAS,  Name: Britta Dombovári Title: Manager, Regulatory Affairs Date: 30. March 2021