TECHNICAL FILE – DECLARATION OF CONFORMITY

DESCRIPTION	Laser Applicators
CLASSIFICATION	Class-IIb

Revision	Effective Date	Originator	Description
A	21 November 2014	Pierre Bounaud	Initial Release
B	23 December 2014	Natalia Shirina	Updated EC Certificate Information
C	29 September 2016	Subhadra Elango	Updated EC Certificate Information
D	27 February 2017	W.Fisher	Updated EC Certificate Information
E	07/26/2018	S.Golle	QMS-08108 Updated DOC template. Updated EC Certification Information Updated Signature information
N/A	06/12/2019	K.Williams	QMS-11525 Refer to REC-001079 Rev A Updated Manufacturer filed to be Legal Manufacturer. Removed Conformity Assessment Route field and added it to the Declaration Statement. Updated the standards to match what is current. Updated Notified Body address and number. Updated Signature field.
F	9/19/2019	Britta Dombovári	QMS-12622 Reviewed and updated Standards listing to reflect to current Techfile-TF-CHATT-006
F	9/19/2019	S. Jean-Baptiste	DOC-08251 Corrected typos in standards
G	See Agile	S. Rimer	Update EC Cert – Renewed / Consolidated EC Certificates. Update of referenced standards and other related information.

DECLARATION OF CONFORMITY	
LEGAL MANUFACTURER	DJO, LLC 1430 Decision Street Vista, CA 92081-8553 U.S.A.
EU AUTHORIZED REPRESENTATIVE	MDSS GmbH Schiffgraben 41 30175 Hannover Germany
PRODUCT	Laser Applicators
PART NUMBER LIST	TF-CHATT-006-3_Laser Applicators Part Number List
CLASSIFICATION	Class-IIb
CONFORMITY ASSESSMENT ROUTE	Annex II (MDD) – Full Quality Assurance
GMDN CODE	60409
UMDNS CODE	27404

WE, THE MANUFACTURER, DJO, LLC, 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)

Applied Standards:	ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
	EN 1041:2008 + A1:2013	Information supplied by the manufacturer with medical devices
	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 10993-1:2018	Biological evaluation of medical devices
	EN 60601-1:2006 / A1:2013 (IEC 60601-1:2005/A1:2012)	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 60601-2-22:1996	Medical electrical equipment. Particular requirements for safety. Specification for diagnostic and therapeutic laser equipment
	IEC 62304:2006 / Amd 1:2015	Medical Device software - software life-cycle processes
	IEC 62366:2014	Medical Devices - Application of usability engineering to medical devices
	MEDDEV 2.7.1 Rev.: 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies

NOTIFIED BODY	**BSI Group** Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands Telephone: +31 20 346 0780 **No: 2797**
EC CERTIFICATE(S)	EC Certificate #: CE 678711 Initial Certification Date: 2018-07-20 Certificate Effective Date: 2019-12-12 Certificate Expiration Date: 2024-05-26
PLACE OF ISSUE	Vista, CA, USA
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO, LLC.: Name: Jim Pomeroy Title: VP, Global Quality Assurance and Regulatory Affairs Date: 2019-12-12