TECHNICAL FILE – DECLARATION OF CONFORMITY

DESCRIPTION	VitalStim Plus
CLASSIFICATION	Class IIa

Revision	Effective Date	Originator	Description
A	October 5, 2015	N. Shirina	Initial Release
B	October 15, 2015	N. Shirina	Updated EC Certificate revision level and conformity assessment route
C	September 29, 2016	S.Elango	Updated EC Certificate information
D	27 February 2017	W.Fisher	Updated EC Certificate information
E	24 October 2017	L. Mullens	Updated to reflect latest 1000.020 Rev B template and new PC Software (13-5923-PC-SW)
F	See Agile	S.Elango	QMS-08108 Update EC certificate information and signature. Update to current template form 1000.020 Rev. B
G	27 March 2019	Originator: K. Lakshmi _____ RA Approver: Ehab Esmail _____ QA Approver: Jim Pomeroy _____	Updated Manufacturer field to include Legal Manufacturer. Removed Conformity Assessment Route and added it to the Declaration statement. Updated the standards section to include the most recent applicable standards. Updated Signature field. Updated Notified Body field and EC Cert field.
H	12 October 2020	S. Jean-Baptiste	QMS-12624 Reviewed and updated Standards listing to reflect to current Techfile-TF-CHATT-017 To update Certificate reference and expiry date.
J	See Agile	K. Lakshmi	QMS- 16723 Update Notified body number in notified body field and the UMDNS code.

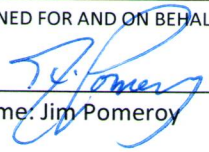
DECLARATION OF CONFORMITY

MANUFACTURER	DJO, LLC 1430 Decision Street Vista, CA 92081-8553 U.S.A.
EU AUTHORIZED REPRESENTATIVE (MDD)	MDSS GmbH Schiffgraben 41 30175 Hannover Germany
PRODUCT	CHATTANOOGA VITALSTIM PLUS ELECTROTHERAPY SYSTEM.
PART NUMBER LIST	TF-CHATT-017-3 VitalStim Plus Electrotherapy System-Part Number List
MDD CLASSIFICATION **RED CLASSIFICATION**	Class IIa
GMDN CODE	46573
UMDNS CODE	13775

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)
- 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**	Medical devices - Quality management systems - Requirements for regulatory purposes
	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
	EN ISO 10993-1:2009/AC:2010	Biological Evaluation of 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
	EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)	Medical Electrical Equipment, Part 1: General Requirements for Safety and essential performance
	IEC 60601-2-10:2012	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
	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
	IEC 62366:2014	Medical devices – Application of Usability Engineering to Medical Devices
	IEC 60601-1-6:2013	Medical electrical equipment -Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability

	IEC 60601-1-11:2010	Medical electrical equipment -Part 1-11: General requirements for basic safety and essential performance - Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment
	IEC 62304:2006	Medical Device Software - Software life-cycle processes
	MEDDEV 2.7.1 Rev 4	Clinical Evaluation: A Guide for Manufacturers and NotifiedBodies
	EN 300 328 V1.7.1 (2006-10)	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques
	EN 301 489-1 V1.8.1 (2008-04)	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
	EN 301 489-17 V2.1.1 (2009-05)	Electro Magnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems
NOTIFIED BODY (MDD)	**BSI Group** Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands Telephone: +31 20 346 0780 No: 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: Vice President, Regulatory Affairs & Quality Date: October 27, 2020	