TECHNICAL FILE – DECLARATION OF CONFORMITY

DESCRIPTION	Chattanooga Primera – TENS & NMES Stimulator
CLASSIFICATION	Class IIa

Revision	Effective Date	Originator	Description
0/ A	3.26.14	G. Flores	Initial Release
B	1.26.2016	N. Shirina	Update to comply with additional requirements as a virtual manufacturer
C	10.3.2016	S. Elango	Update EC Certificate information
D	See Agile	S. Rimer	Update EC Cert – Renewed / Consolidated EC Certificates. Update of referenced standards and other related information.

DECLARATION OF CONFORMITY		
MANUFACTURER	DJO, LLC 1430 Decision Street Vista, CA 92081-8553 U.S.A.	
EU AUTHORIZED REPRESENTATIVE	MDSS GmbH Schiffgraben 41 30175 Hannover Germany	
PRODUCT	CHATTANOOGA PRIMERA – TENS & NMES Stimulator	
CLASSIFICATION	Class IIa	
CONFORMITY ASSESSMENT ROUTE	Annex II (MDD) – Full Quality Assurance	
GMDN CODE	46573	
UMDNS CODE	13-775	
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)		
STANDARDS APPLIED	EN ISO 13485:2016	Medical Devices – Quality management system – 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
	EN ISO 10993-1:2018	Biological Evaluation of medical devices – Part 1: General requirements for basic safety and essential performance
	EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)	Medical Electrical Equipment, Part 1: General Requirements for Safety and essential performance
	IEC60601-2-10:1987 + A1:2001 + AC:2002	Particular requirements for the safety of nerve and muscle stimulators
	EN 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 60601-1-6:2010 + A1:2015	Medical electrical equipment -Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
	IEC 62366:2014	Medical devices – Application of Usability Engineering to Medical Devices
	IEC 60601-1-11:2015	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
	EN 62304:2006 / Amd1:2015	Medical Device Software - Software life-cycle processes

	EN 62133: 2013	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
	MEDDEV 2.7.1 Rev 3	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	