TECHNICAL FILE – DECLARATION OF CONFORMITY

DESCRIPTION	TENS Stimulators
CLASSIFICATION	Class IIa

Revision	Effective Date	Originator	Description
A	03 March 2015	Pierre Bounaud	Initial Release
B	June 30, 2016	D. Zaczek	Updated for 3rd edition Added Cefar Femina, Cefar Peristim Pro, and Cefar Rehab X2 Updated GMDN and UMDNS codes
C	March 2, 2018	N. Li	Update EC Certificate revision number Update to current revsion of 1000.020
D	See Agile	S. Golle	QMS-08511 Updating EC certificate number and standards applied. Added product number list.
E	See Agile	T. Allard	QMS-10244 Addition of Chattanooga CEFAR PRIMO PRO, update of NB and standards list

DECLARATION OF CONFORMITY		
MANUFACTURER	**DJO France SAS** Centre Européen de Frêt 3 rue de Béthar 64990 Mouguerre France	
EU AUTHORIZED REPRESENTATIVE	MDSS GmbH Schiffgraben 41 30175 Hannover Germany	
PRODUCT	TENS Stimulators: Cefar Easy, Cefar Basic, Cefar Primo Pro TENS+NMES Stimulators: Cefar Femina, Cefar Peristim Pro, Cefar Rehab X2	
PRODUCT NUMBER LIST	TF-0003-3_ TENS + NMES Stimulators Parts List_Rev D	
CLASSIFICATION	Class IIa, Rule 9	
CONFORMITY ASSESSMENT ROUTE	Annex II – Full Quality Assurance	
GMDN CODE	35372, 46573	
UMDNS CODE	13-782, 13-775	
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 14971:2012	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

	EN 60601-1-11: 2010	Medical electrical equipment - Part 1-11: 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.
	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
	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
NOTIFIED BODY	BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP Tel: +44-345-080-9000	
EC CERTIFICATE(S)	EC Certificate #:CE 681250 Initial certificate Date: 27 July 2018 Certificate Effective Date:23 Jan 2019 Certificate Expiry Date: 23 January 2024	
PLACE OF ISSUE	Mouguerre, France	
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO FRANCE SAS,  Name: Tim Allard Title: Senior Manager Regulatory (Affairs and Compliance) Date: 29 January 2019	