TECHNICAL FILE – DECLARATION OF CONFORMITY

DESCRIPTION	Chattanooga Professional Devices ESM G5 Wired & Wireless
CLASSIFICATION	IIa

Revision	Effective Date	Originator	Description
A	Feb 13, 2018	W Fisher	Initial Release
B	08/20/2018	L Mullens	QMS-08389 Update EC Certificate number to BSI and Update to current template
C	09/18/2018	S. Gully	QMS-08674 Updating revision number for the Part Number List and the Product field to include Wired devices.
D	01/29/2019	T. Allard	QMS-10244 Update DoC with new certificate and added Argentinian part numbers to the part number list.
E	See Agile	S.Pouy	QMS-10998 Addition of 4 Channel Full in product list

DECLARATION OF CONFORMITY		
MANUFACTURER	DJO France SAS, Centre Européen de Frêt, 3 rue de Bethar, 64990 Mouguerre, France	
EU AUTHORIZED REPRESENTATIVE	N/A	
PRODUCT	Chattanooga Wireless Professional Line 2 and 4 Channel Standard,2 Channel Full, 4 Channell Full, Chattanooga Wired Professional Rehab, Tetha and Physio.	
PART NUMBER LIST	TF-FRA-011-3_ Chattanooga Professional Devices ESM G5 Wired & Wireless PL_Rev C	
EC CERTIFICATE CATEGORY	Neuromuscular Stimulators	
CLASSIFICATION	Class IIa Rule 9	
CONFORMITY ASSESSMENT ROUTE	Annex II Full Quality Assurance	
GMDN CODE	46573	
UMDNS CODE	13-775	
We, the manufacturer, DJO FRANCE SAS, declare under sole responsibility that the items 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/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
	EN 62304:2006	Medical Device software - software life-cycle processes
NOTIFIED BODY	BSI Group Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP Telephone: +44 (0) 1908 814844 Fax: +44 (0) 1908 814924 N/O No: 0086	
EC CERTIFICATE(S)	EC Certificate #: CE 681250 Issue date: 2018-07-27 Expiration date: 2024-01-23	
PLACE OF ISSUE	DJO France SAS, Mouguerre, France	
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO FRANCE SAS,  Name: Tim Allard Title: Senior Manager Regulatory (Affairs and Compliance) Date: 3 April 2019	