	TECHNICAL FILE – DECLARATION OF CONFORMITY
DESCRIPTION	Compex Neurostimular Stimulators
CLASSIFICATION	IIa

Revision	Effective Date	Originator	Description
A	02-02-2018	W. Fisher	QMS-06295 Initial Release
B	08/27/2018	S. Gully/S.Golle	QMS-07875 Updating DoC template to 1000.020 Removing Direct Tens from Product list Updating EC Certificate number.
C	02/04/2019	T. Allard	QMS-10244 Update EC Certificate expiry and standards list
D	07/05/2019	T. Allard	QMS- 11014 Update the product models in the product section and update the standards EU REP removed Update document number, description and classification
E	See Agile	T. Allard	QMS-13696 Addition of Decathalon Branded product to range, change of Notified Body Address to Netherlands office.

DECLARATION OF CONFORMITY		
MANUFACTURER	DJO France SAS, Centre Européen de Frêt, 3 rue de Bethar, 64990 Mouguerre, France	
EU AUTHORIZED REPRESENTATIVE (MDD)	N/A	
PRODUCT	Compex Runner, Sport, Fitness, Sport Elite, SP4.0, SP2.0, FIT3.0, FIT1.0 (also known SP 4.0, SP 2.0, Fit 3.0, Fit 1.0)	
PART NUMBER LIST	TF-FRA-008-3 CL14 & Tractical Compex Part Number List	
MDD CLASSIFICATION **RED CLASSIFICATION**	Class IIa Rule 9	
CONFORMITY ASSESSMENT ROUTE	Annex VII (MDD)	
GMDN CODE	46573	
UMDNS CODE	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) • 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 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 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 10993-1:2009/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

NOTIFIED BODY	BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel + 31 20 346 0780
EC CERTIFICATE(S)	EC Certificate #:CE 681250 Initial certificate Date: 27 July 2018 Certificate Effective Date:26 February 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: January 3, 2020