

DECLARATION OF CONFORMITY		
DOCUMENT NUMBER	DCE-0008 v6.00	
MANUFACTURER	DJO France SAS, Centre Européen de Frêt, 3 rue de Bethar, 64990 Mouguerre, France	
EU AUTHORIZED REPRESENTATIVE	MDSS GmbH Schiffgraben 41 30175 Hannover Germany	
EC CERTIFICATE CATEGORY	Neuromuscular Stimulators	
CLASSIFICATION	Class IIa Rule 9	
CONFORMITY ASSESSMENT ROUTE	Annex II Full Quality Assurance	
GMDN CODE	46573	
UMDNS CODE	N/A	
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, and • 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), and • Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on Waste Electrical and Electronic Equipment (WEEE, Recast)		
STANDARDS APPLIED	ISO 13485:2003	Medical Devices – Quality management system – Requirements for regulatory purposes
	EN ISO 13485:2012	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 980:2008	Symbols for use in the labeling of medical devices
	ISO 15223-1:2012	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	ISO 10993-1:2009	Biological Evaluation of medical devices – Part 1: General requirements for basic safety and essential performance
	EN 60601-1:2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
	FCC 15.249: 2007	Operation within the bands 902-928 MHz, 2400-2483.5 MHz, 5725-5875 MHz and 24.0-24.25 GHz. RSS-210, Issue 7, 2007

	EN 301 489-3:2002	Electromagnetic compatibility and radio spectrum matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for short range devices (SRD) operating on frequencies between 9 KHZ and 246 GHZ
	EN 300 440-2:2010	Electromagnetic compatibility and radio spectrum matters (ERM); short range devices; radio equipment to be used in the 1 GHZ to 40 GHZ frequency range; Part 2: Harmonized EN covering the Essential Requirements of Article 3.2 of the R&TTE Directive.
	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
	IEC 62366: 2014	Medical Devices - Application of usability engineering to medical devices
NOTIFIED BODY	Intertek AMTAC Knowlhill, Milton Keyes, UK No: 0473	
EC CERTIFICATE(S)	EC Certificate #: 1055 CE Issue date: 15 September 2010 Expiration date: 14 January 2019	
PLACE OF ISSUE	DJO UK Ltd, Guildford, United Kingdom	
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO FRANCE SAS,  Name: Lawrence Brookfield Title: Regulatory Affairs Manager International Date: 10 November 2014	

Product Family: Consumer Electrostimulation Equipment

Product Code	Description
P518416	COMPEX RUNNER (EU plug France only)
2518102	COMPEX RUNNER (UK plug)
2518111	COMPEX RUNNER (US plug)
2518120	COMPEX RUNNER (AUS plug)
2518162	COMPEX RUNNER (EU plug)
2525116	COMPEX FIT (EU plug)
2525117	COMPEX FIT (US plug)
2525118	COMPEX FIT (UK plug)
2525120	COMPEX FIT (AUS plug)
2527116	DIRECT TENS (EU plug)
2529116	COMPEX WIRELESS (EU plug)
2529203	COMPEX WIRELESS – TIME Signature Series (EU plug)
2529660	COMPEX WIRELESS (US, UK & AUS plug)
2530116	ONE by Compex (EU plug)
2530660	ONE by Compex (US plug)
2530960	ONE by Compex (UK plug)
506102	COMPEX SPORT ELITE (UK plug)
506106	COMPEX SPORT ELITE (US plug)
506116	COMPEX SPORT ELITE (EU plug)
506120	COMPEX SPORT ELITE (AUS plug)
506416	COMPEX SPORT ELITE WHITE EDITION
507102	COMPEX FULL FITNESS (UK plug)
507106	COMPEX FULL FITNESS (US plug)
507116	COMPEX FULL FITNESS (EU plug)
508102	COMPEX VITALITY (UK plug)
508106	COMPEX VITALITY (US plug)
508116	COMPEX VITALITY (EU plug)
508120	COMPEX VITALITY (AUS plug)
509102	COMPEX MI SPORT (UK plug)
509106	COMPEX MI SPORT (US plug)

Product Code	Description
509116	COMPEX MI SPORT (EU plug)
509120	COMPEX MI SPORT (AUS plug)
510102	COMPEX MI FITNESS (UK plug)
510106	COMPEX MI FITNESS (US plug)
510116	COMPEX MI FITNESS (EU plug)
510120	COMPEX MI FITNESS (AUS plug)
514109	COMPEX ENERGY II EU (UK plug)
514111	COMPEX ENERGY II EU (US plug)
514116	COMPEX ENERGY II EU (EU plug)
514120	COMPEX ENERGY II EU (AUS plug)
515109	COMPEX PERFORMANCE EU (UK plug)
515111	COMPEX PERFORMANCE EU (US plug)
515116	COMPEX PERFORMANCE EU (EU plug)
515120	COMPEX PERFORMANCE EU (AUS plug)
2536116	SET SP40 MULTILINGUAL EU PLUG
2536660	SET SP40 MULTILINGUAL US PLUG
2536960	SET SP40 MULTILINGUAL UK PLUG
2536120	SET SP40 MULTILINGUAL AUS PLUG
2535116	SET SP20 MULTILINGUAL EU PLUG
2535660	SET SP20 MULTILINGUAL US PLUG
2535960	SET SP20 MULTILINGUAL UK PLUG
2535120	SET SP20 MULTILINGUAL AUS PLUG
2534116	SET FIT30 MULTILINGUAL EU PLUG
2534660	SET FIT30 MULTILINGUAL US PLUG
2534960	SET FIT30 MULTILINGUAL UK PLUG
2534120	SET FIT30 MULTILINGUAL AUS PLUG
2533116	SET FIT10 MULTILINGUAL EU PLUG
2533660	SET FIT10 MULTILINGUAL US PLUG
2533960	SET FIT10 MULTILINGUAL UK PLUG
2533120	SET FIT10 MULTILINGUAL AUS PLUG
2539116	COMPEX WIRELESS SP80 MULTILINGUAL EU PLUG
2539660	COMPEX WIRELESS SP80 MULTILINGUAL US PLUG
2539960	COMPEX WIRELESS SP80 MULTILINGUAL UK PLUG
2539120	COMPEX WIRELESS SP80 MULTILINGUAL AUS PLUG

Product Code	Description
2538116	COMPEX WIRELESS SP60 MULTILINGUAL EU PLUG
2538660	COMPEX WIRELESS SP60 MULTILINGUAL US PLUG
2538960	COMPEX WIRELESS SP60 MULTILINGUAL UK PLUG
2538120	COMPEX WIRELESS SP60 MULTILINGUAL AUS PLUG
2537116	COMPEX WIRELESS FIT50 MULTILINGUAL EU PLUG
2537660	COMPEX WIRELESS FIT50 MULTILINGUAL US PLUG
2537960	COMPEX WIRELESS FIT50 MULTILINGUAL UK PLUG
2537120	COMPEX WIRELESS FIT50 MULTILINGUAL AUS PLUG