DECLARATION OF CONFORMITY

MANUFACTURER	**DJO FRANCE SAS** 3 rue de Bethar Centre Européen de Frêt 64990 Mouguerre FRANCE
EU AUTHORIZED REPRESENTATIVE (MDD)	N/A
PRODUCT	Intelect Neo Clinical Therapy System: • Neo Module Stim Channels 1 & 2 • Neo Module Ultrasound • Neo Module Stim Channels 3 & 4 • Neo Module Stim Channels 1 & 2 + EMG • Neo Module Laser
PART NUMBER LIST	Refer to TF-CHATT-015-3 Rev. B.
MDD CLASSIFICATION	Class IIb
CONFORMITY ASSESSMENT ROUTE	Annex II – Full Quality Assurance
GMDN CODE	46571, 11248, 37794, 35147
UMDNS CODE	13-775, 17-908, 17-516

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	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 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	Biological Evaluation of medical devices – Part 1: General requirements for basic safety and essential performance
	IEC 60601-1:2005+ Corr. 1 (2006) + Corr. 2 (2007)	Safety Requirements for Medical Electrical Systems. Ed. 3
	IEC 60601-1-2:2007	Electromagnetic Compatibility – Requirements and Tests. Ed. 3
	IEC 62366:2007	Medical devices – Application of usability
	IEC 62304:2006	Medical device software – Software life-cycle processes
	ASTM D4169-09	Standard practice for performing testing of shipping containers and systems
NOTIFIED BODY	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP	

Digitally signed by Prodan Sveatoslav
Date: 2024.06.10 10:18:29 EEST
Reason: MoldSign Signature
Location: Moldova

	Amsterdam Netherlands 2797
EC CERTIFICATE(S)	CE 681250
PLACE OF ISSUE	64990 Mouguerre, France
SIGNATURE	SIGNED FOR AND ON BEHALF OF **DJO FRANCE SAS** Name: Britta Dombovári Title: Regulatory Affairs Manager Date: December 19, 2018

Vu pour certification
matérielle de la Signature
de M.me Britta DOMBOVARI
BAYONNE, le 28/08/2020
POUR LE PRESIDENT DE LA CHAMBRE
DE COMMERCE ET D'INDUSTRIE
DE BAYONNE PAYS BASQUE

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BAYONNE PAYS BASQUE
VIGENT FIDE
1724

Pour le Président de la Chambre
de Commerce et d'Industrie
de Bayonne Pays Basque

F. HARRIAGUE