	TECHNICAL FILE – DECLARATION OF CONFORMITY
DESCRIPTION	Intelect Neo Clinical Therapy System
CLASSIFICATION	Class-IIb

Revision	Effective Date	Originator	Description
A	See Agile	S.Elango	QMS-08108: Initial Release
B	18 Dec 2018	L.Krishna	EC Certificate field change QMS-09871
C	See Agile	S. Rimer	Update EC Cert – Renewed / Consolidated EC Certificates. Update of referenced standards and other related information.

DECLARATION OF CONFORMITY	
MANUFACTURER	DJO, LLC 1430 Decision Street Vista, CA 92081-8553 U.S.A.
EU AUTHORIZED REPRESENTATIVE (MDD)	MDSS GmbH Schiffgraben 41 30175 Hannover Germany
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
MDD CLASSIFICATION	Class-IIb
CONFORMITY ASSESSMENT ROUTE	Annex II (MDD) – Full Quality Assurance
GMDN CODE	46571, 11248, 37794, 35147
UMDNS CODE	13-775, 17-908, 17-516

WE, THE MANUFACTURER, DJO LLC, 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 13485:2016	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 + A1:2013	Information supplied by the manufacturer with medical devices
	ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	EN ISO 10993-1:2018	Biological Evaluation of medical devices – Part 1: General requirements for basic safety and essential performance
	EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)	Safety Requirements for Medical Electrical Systems. Ed. 3
	IEC 60601-1-2:2014	Electromagnetic Compatibility – Requirements and Tests
	IEC 60601-2-5:2000	Medical electrical equipment—Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment
	IEC 60601-2-10:1987 + A1:2001+AC:2002	Medical electrical equipment - Part 2: Particular Requirements for the safety of nerve and muscle stimulators
	IEC 62366:2014	Medical devices – Application of usability
	IEC 62304:2006 / Amd 1:2015	Medical device software – Software life-cycle processes
	MEDDEV 2.7.1 Rev.: 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
	ASTM D4169	Standard practice for performing testing of shipping containers and systems

NOTIFIED BODY	**BSI Group** Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands Telephone: +31 20 346 0780 **No: 2797**
EC CERTIFICATE(S)	EC Certificate #: CE 678711 Initial Certification Date: 2018-07-20 Certificate Effective Date: 2019-12-12 Certificate Expiration Date: 2024-05-26
PLACE OF ISSUE	Vista, CA, USA
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO, LLC.:  Name: Jim Pomeroy Title: VP, Global Quality Assurance and Regulatory Affairs Date: 2019-12-12