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

Revision	Effective Date	Originator	Description
A	19 Nov 2013	L.Trotter	Initial Release
B	19 Dec 2013	L.Trotter	Class I and Class IIb products listed on separate declarations; updated GMDN & UMDNS codes; corrected device names to match Oracle
C	05 Feb 2014	L.Trotter	Correct Annex on DOC for Class I products
D	31 May 2014	L.Trotter	Correct vacuum leadhose and electrode classification (Class IIb to Class I) and replace obsolete GMDN codes
E	25 Nov 2014	P. Bounaud	Moved Part Numbers and GMDN/UMDNS codes to Part Number List Attachment; added RoHS to Declaration; updated Standards Applied
F	20 Aug 2018	L Mullens	QMS-08389 Update EC Certificate number to BSI
G	30 Jan 2019	T. Allard	QMS-10244 Update EC Certificate expiry and standards list
H	11. August 2020	T. Allard	QMS-11958 EU AUTHORIZED REPRESENTATIVE removed
J	See Agile	B. Dombovari	QMS-18480 To update/correct CE Certificate issue date for class II products To update NB information

DECLARATION OF CONFORMITY	
MANUFACTURER	DJO FRANCE SAS CENTRE EUROPÉEN DE FRÊT. 3 RUE DE BÉTHAR 64990 MOUGUERRE, FRANCE
PRODUCT	Intelect Neo Clinical Therapy System: POWERCORD VACUUM LEADHOSE KIT VACUUM ELECTRODE KIT VACUUM SPONGE KIT VACUUM MODULE ELECTRODE/LEADHOSE KIT VACUUM PLUG KIT UPGRADE KIT INTELECT NEO
PART NUMBER LIST	70021-70026 - POWERCORD 70030-70033 - VACUUM LEADHOSE KIT 70034-70036 - VACUUM ELECTRODE KIT 70037-70039 - VACUUM SPONGE KIT 70040 - VACUUM MODULE ELECTRODE/LEADHOSE KIT 70041 - VACUUM PLUG KIT 70051 - UPGRADE KIT INTELECT NEO
MDD CLASSIFICATION **RED CLASSIFICATION**	Class I
CONFORMITY ASSESSMENT ROUTE	Annex VII
GMDN CODE	35751, 47711, 61170
UMDNS CODE	16-312, 11-454, 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, 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)

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

NOTIFIED BODY	N/A –Class I without sterility or measuring function
EC CERTIFICATE(S)	N/A –Class I without sterility or measuring function
PLACE OF ISSUE	Mouguerre France
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO FRANCE SAS,  Name: Britta Dombovári Title: Manager, Regulatory Affairs Date: March 30, 2021

DECLARATION OF CONFORMITY		
MANUFACTURER	DJO FRANCE SAS CENTRE EUROPÉEN DE FRÊT. 3 RUE DE BÉTHAR 64990 MOUGUERRE, FRANCE	
EU AUTHORIZED REPRESENTATIVE (MDD)	N/A	
PRODUCT	Intelect Neo Clinical Therapy System: • INTELECT NEO HEAD • NEO MODULE VACUUM • ULTRASOUND APPLICATORS	
CLASSIFICATION	Class IIb	
CONFORMITY ASSESSMENT ROUTE	Annex II – Full Quality Assurance	
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, 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)		
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	EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
	EN 1041:2008	Information supplied by the manufacturer with medical devices
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	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 (MDD)	BSI Group Say Building, John M. Keynesplein 9 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 780 NB No: 2797	
EC CERTIFICATE(S)	EC Certificate Nr. : CE 681250 Issue date : 2020-09-22 Expiration date : 2024-01-23	
PLACE OF ISSUE	Mouguerre France	
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO FRANCE SAS,  Name: Britta Dombovári Title: Manager, Regulatory Affairs Date: April 6, 2021	