	TECHNICAL FILE – DECLARATION OF CONFORMITY
DESCRIPTION	Hydrocollator Heating & Chilling Units and Hot & Cold Packs
CLASSIFICATION	I

Revision	Effective Date	Originator	Description
A	30 September 2014	Pierre Bounaud	Initial Release
B	08/09/2018	L Mullens	QMS-08235 Update parts list reference, update footer to template, update UMDNS/GMDN codes
C	See Agile	B. Dombovári	QMS-18269 To include Chilling units and cold packs in the product section Clarify that MDSS is the EU Authorized Rep. for OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITY COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES Update of standards reference EN ISO 13485 to reflect current standard applied Update description to Hydrocollator Heating & Chilling Units and Hot & Cold Packs Correction of typos.

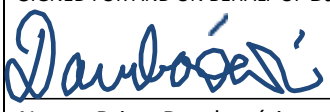
DECLARATION OF CONFORMITY	
MANUFACTURER	DJO, LLC 1430 Decision Street Vista, CA 92081-8553 U.S.A.
EU AUTHORIZED REPRESENTATIVE For OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITY COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL	MDSS GmbH Schiffgraben 41 30175 Hannover Germany
PRODUCT	Hydrocollator Heating & Chilling Units, Hot & Cold Packs and accessories
CLASSIFICATION	Class I
CONFORMITY ASSESSMENT	Annex VII
GMDN CODE	38469, 34971, 15571, 36034
UMDNS CODE	16-509, 12-566, 16-207, 17-457

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)

STANDARDS APPLIED	EN ISO 13485:2016	Medical Devices – Quality management system – Requirements for regulatory purposes
	EN ISO 14971:2012 (ISO 14971:2007)	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
	EN 50419:2005	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
	ISO 7010:2011	Graphical symbols - Safety colours and safety signs
	EN ISO 10993-1:2009/ AC:2010 (ISO 10993-1:2009)	Biological Evaluation of medical devices – Part 1: General requirements for basic safety and essential performance
	EN 60601-1:1990 including A1 (1993), A2 (1995), A11 (1993), A12 (1993), and A13 (1996) (IEC 60601-1:1988 + A1:1991 + A2:1995	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

	EN 60601-1-2:2007 (IEC 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
	EN 60601-1-6: 2010 (IEC 60601-1-6:2010)	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
	IEC 62366 Ed. 1.1:2014	Medical devices – Application of usability engineering to medical devices
	UL 61010-1:2010	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use – Part 1: General Requirements
	MEDDEV 2.7.1 Rev 3	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
	Uniform Freight Classification Rule 41 / National Motor Freight Classification Item 222	

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	Vista, California, USA
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO, LLC  Name: Britta Dombovári Title: Manager Regulatory Affairs, International Date: March 11th, 2021