TECHNICAL FILE – DECLARATION OF CONFORMITY

DESCRIPTION	Cold Therapy
CLASSIFICATION	Class IIa

Revision	Effective Date	Originator	Description
A	7/26/2018	L. Mullens	QMS-08108: Initial Release
B	20 Aug 2018	L. Mullens	QMS-08288: update EC Cert number
C	27 April 2020	S. Rimer	QMS-13911:update EC Cert dates. Update EC Cert – Renewed/Consolidated EC Certificates. Update of referenced standards and other related information.
D	See Agile	K. Lakshmi	QMS-14928: Add Brand Name AIRCAST

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	
BRAND NAME	AIRCAST	
PRODUCT	CryoCuff IC Cooler DonJoy Clear3	
PART NUMBER LIST	TF-DJO-006-3	
MDD CLASSIFICATION	Class IIa	
CONFORMITY ASSESSMENT ROUTE	Annex II (MDD)– Full Quality Assurance	
GMDN CODE	42463	
UMDNS CODE	17777	

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	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
	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)	Medical electrical equipment – Part 1: General Requirements for Safety
	BS EN 60601-1-6:2010 + A1:2015	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
	IEC 60601-1-11:2015	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 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
	IEC 62366:2014	Medical devices – Application of usability Engineering to Medical Devices
	ASTM D4169	Standard practice for performing testing of shipping containers and systems
	MEDDEV 2.7.1 Rev.: 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
NOTIFIED BODY (MDD)	**BSI Group** Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands Tel: + 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: 26th May 2020	