




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	
<p>WE, THE MANUFACTURER, DJO, LLC., DECLARE UNDER SOLE RESPONSIBILITY THAT THE ITEM TO WHICH THIS DECLARATION IS RELATED IS IN CONFORMITY WITH:</p> <ul style="list-style-type: none"> • 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.:  <hr/> Name: Jim Pomeroy Title: VP, Global Quality Assurance and Regulatory Affairs Date: 26 th May 2020	