TECHNICAL FILE – DECLARATION OF CONFORMITY

DESCRIPTION	Intermittent Pneumatic Compression Devices
CLASSIFICATION	Class-IIa

Revision	Effective Date	Originator	Description
A	21 Nov 2014	JBeasley	Initial Release
B	04 Feb 2015	LTrotter	Correction of trade names and GMDN codes; update EC Cert info
C	23 May 2016	RDaoud	Updated signature field
D	29 September 2016	SElango	EC Certificate Information Update
E	27 February 2017	W.Fisher	EC Certificate Information Update
F	28 January 2019	S.Elango	QMS-10223- See Agile for more information Notified Body, EC Certificate, and signature Information Updated. Update to current template form 1000.020 Rev B.
G	26 March 2019	Originator: S. Gully RA Approver: Ehab Esmail QA Approver: Jim Pomeroy	Updated Manufacturer field to include Legal Manufacturer. Removed Conformity Assessment Route and added it to the Declaration statement. Corrected the GMDN code. Updated the standards section to include the most recent applicable standards. Updated Signature field.
H	See Agile	S.Baptiste	QMS-12626 Reviewed and updated Standards listing to reflect to current TechFile-TF-DJO-002
J	See Agile	S. Rimer	Update EC Cert – Renewed / Consolidated EC Certificates. Update of referenced standards and other related information.

DECLARATION OF CONFORMITY	
LEGAL MANUFACTURER	DJO, LLC 1430 Decision Street Vista, CA 92081-8553 U.S.A.
EU AUTHORIZED REPRESENTATIVE	MDSS GmbH Schiffgraben 41 30175 Hannover Germany
PRODUCT	Intermittent Pneumatic Compression Devices (AIRCAST Brand) • VenaFlow Elite • Venaflow Elite, S- Mode
PART NUMBER LIST	TF-DJO-002-3 List of Models and Accessories
MDD CLASSIFICATION	Class-IIa
CONFORMITY ASSESSMENT ROUTE	Annex II (MDD) – Full Quality Assurance
GMDN CODE	10696
UMDNS CODE	10-849

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
	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)	Medical electrical equipment - Part 1: General requirements for safety
	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. Ed. 4
	BS EN 60601-1-6:2010 + A1:2015	Medical electrical equipment Part 1-6: General requirements for safety - Collateral Standard: Usability.
	IEC 62366:2014	Medical Devices - Application of usability engineering to medical device

	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
	EN 62133: 2013	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
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	