DJO	TECHNICAL FILE – DECLARATION OF CONFORMITY
DESCRIPTION	Traction and Decompression Therapy Systems
CLASSIFICATION	This technical documentation applies to both Class-I and Class-IIa medical devices

Revision	Effective Date	Originator	Description
A	11 Nov 2014	J. Beasley, Founder and Senior Consultant, MedTech Review, LLC	Initial Release, MedTech Review, LLC revisions to TF-CHATT-008
B	19 Dec 2014	N. Shirina	Updated EC Certificate Information
C	29 September 2016	S. Elango	Updated EC Certificate Information
D	14 April 2017	L. Brookfield	Updated GMDN and UMDNS section of certificate
E	23 July 2018	L. Mullens	QMS-06812 Update Class IIa section information
F	26 July 2018	S. Golle	QMS-08108 Updated the EC Certification Information and signature information.
G	27 March 2019	Originator: K. Lakshmi RA Approver: Ehab Esmail QA Approver: Jim Pomeroy	Updated Manufacturer field to include Legal Manufacturer and part list. Removed Conformity Assessment Route and added it to the Declaration statement. Updated the standards section to include the most recent applicable standards. Updated Signature field.
H	19 September 2019	B.Dombovari	QMS-12623 Reviewed and updated Standards listing to reflect to current Techfile-TF-CHATT-008
H	19 September 2019	S. Jean-Baptiste	DOC-08251 Corrected typos in standards
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 (MDD)	MDSS GmbH Schiffgraben 41 30175 Hannover Germany	
PRODUCT	Traction and Decompression Therapy Accessories	
PART NUMBER LIST	TF-CHATT-008_Traction_AccDoc_List of Models and Accessories	
MDD CLASSIFICATION	Class-I	
CONFORMITY ASSESSMENT ROUTE	Annex-VII (MDD)	
GMDN CODE	46526, 59227, 41573, 41542, 45533, 35477, 45534, 10396, 45538	
UMDNS CODE	14100, 15292, 14931, 11093, 14108, 13967, 4073, 14151	
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. CONFORMITY ASSESSMENT ROUTE IS ANNEX VII • 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	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
	IEC 60601-2-40:1998	Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment
	IEC 62304:2006 / Amd 1:2015	Medical device software – Software life-cycle processes
	IEC 62366:2014	Medical Devices - Application of usability engineering to medical devices
	MEDDEV 2.7.1 Rev.: 4	Clinical Evaluation: A guide for manufacturers and notified bodies
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, CA United States of America	
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO, LLC, Name: Jim Pomeroy Title: VP, Global Quality and Regulatory Date: 2019-12-12	

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
PRODUCTS	• Triton Traction, Tru-Trac Traction, Triton w/EMG Pkg • EMG Triton Pkg
PART NUMBER LIST	TF-CHATT-008-3_Traction and Decompression Therapy Systems Models, Accessories
MDD CLASSIFICATION **RED CLASSIFICATION**	Class-IIa
CONFORMITY ASSESSMENT ROUTE	Annex II (MDD) – Full Quality Assurance
GMDN CODE	45538
UMDNS CODE	14108

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	Safety Requirements for Medical Electrical Systems. Ed. 3
	IEC 60601-1-2: 2014	Electromagnetic Compatibility – Requirements and Tests. Ed. 4
	IEC 60601-2-40:1998	Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment
	IEC 62304:2006 / Amd 1:2015	Medical device software – Software life-cycle processes
	IEC 62366:2014	Medical Devices - Application of usability engineering to medical devices
	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 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