UNDER MDR 2017/745: DECLARATION OF CONFORMITY **FR:** EN VERTU DU MDR 2017/745 : DECLARATION DE CONFORMITE **DE:** GEMÄß MDR 2017/745: KONFORMITÄTSERKLÄRUNG **ES:** SEGUN MDR 2017/745: DECLARACION DE CONFORMIDAD	
FOR TECHNICAL FILE: **FR:** POUR LA FICHE TECHNIQUE : **DE:** FÜR TECHNISCHE UNTERLAGEN: **ES:** PARA EL ARCHIVO TÉCNICO:	TF-DJO-011-C
DESCRIPTION: **FR:** DESCRIPTION : **DE:** BESCHREIBUNG: **ES:** DESCRIPCIÓN:	SOFTGOODS - HEAD AND BODY
RISK CLASSIFICATION: **FR:** CLASSIFICATION DES RISQUES : **DE:** RISIKOKLASSIFIZIERUNG: **ES:** CLASIFICACIÓN DE RIESGOS:	Class I

REVISION **FR:** REVISION **DE:** REVISION **ES:** REVISION	**CHANGE NO.** **N° DE MODIFICATION** **ÄNDERUNGSNR.** **N.° DE CAMBIO**	**DESCRIPTION** **DESCRIPTION** **BESCHREIBUNG** **DESCRIPCIÓN**	**DATE** **DATE** **DATUM** **FECHA**
A	Not controlled in Agile	Separate DOC from Tech File Rev control as attachment to simplify document updates. Additions of GMDNS and UMDNS codes	08/01/2013
B	Not controlled in Agile	Updated signatory to be Jeff Monroe Senior Manager Global Quality Systems	01/24/2014
C	Not controlled in Agile	Revised tech file and update DOC to reflect Mark Stavro, Senior Director Global Regulatory Affairs, include Usability Standard as applicable, etc.	6/26/2015
D	Not controlled in Agile	Updated GMDNS and UMDNS codes.	1/26/2016
E	QMS-05921	Adding Consumer's Bionic Back Wrap No change to GMDNs or UMDNs codes	8/10/2016
F	QMS-07958	Update to current template. Addition of: Bionic Reel-Adjust Back Brace, Elastic Back Wrap, Waist Trimmer, Abdominal Support, and Stabilizing Back Support (DJP & DJA) to the parts number list and update of model list (part number) revision on DOC.	7/26/2018
G	QMS-10125	Updated signatory; Updated standards to current revisions; Delete "as amended up to" portion of the "All relevant provisions" statement.	17 Jan 2019

REVISION FR: REVISION DE: REVISION ES: REVISION	CHANGE NO. N° DE MODIFICATION ÄNDERUNGSNR. N.° DE CAMBIO	DESCRIPTION DESCRIPTION BESCHREIBUNG DESCRIPCIÓN	DATE DATE DATUM FECHA
H	QMS-13368	Obsolete products removed Update to include TENS Lumbar Belt, Powerstrap Lumbar Belt, C2+ and MyBabystrap products	29 May 2020
J	QMS-17273	Transfer of information into new MDR template, total re-write.	01/28/2020
K	QMS-18303	Update to align with revision of TF-DJO-011-C-MASTER-DATA, which includes Isoform Group 2 back braces.	09/08/2021
L	QMS-23079	Add ladystrap and change address	03/30/2022
M	QMS-23891	Update conformity assessment route and update to current template, total rewrite.	07/11/2022
N	QMS-25139	Update of the signature date due to the addition of new products	17-Nov-2022
P	QMS-25871	Amended to add SRN for authorized representative. Add to rule to risk classification, Clarification of conformity assessment, added Intended Use row, general formatting	12/15/2022
R	QMS-28281	Updated the technical documentation by adding new SKU (SPINOSTRAP)	August 30th, 2023
S	QMS-29285	DJO LLC SRN added	October 31st, 2023
T	QMS-30072	Updated the technical documentation by adding new SKUs (Lumboforce)	January 1st, 2024
U	QMS-31602	Updated the technical documentation by adding new SKUs (Lumboforce project)	See agile

DECLARATION OF CONFORMITY **FR:** DÉCLARATION DE CONFORMITÉ **DE:** KONFORMITÄTSERKLÄRUNG **ES:** DECLARACIÓN DE CONFORMIDAD	
MANUFACTURER **FR:** FABRICANT **DE:** HERSTELLER **ES:** FABRICANTE	DJO, LLC 5919 Sea Otter Place Suite 200 Carlsbad, CA 92010 USA
SRN	US-MF-000034062
EU AUTHORIZED REPRESENTATIVE **FR:** REPRÉSENTANT AGRÉÉ POUR L'UNION EUROPÉENNE **DE:** AUTORISIERTER VERTRETER IN DER EU **ES:** REPRESENTANTE AUTORIZADO EN LA UE	MDSS GmbH Schiffgraben 41 30175 Hannover Germany
SRN	DE-AR-000005430
PRODUCT **FR:** PRODUIT **DE:** PRODUKT **ES:** PRODUCTO	SOFTGOODS - HEAD AND BODY
INTENDED USE **FR:** UTILISATION PREVUE **DE:** ZWECKBESTIMMUNG **ES:** FINALIDAD PREVISTA	DJO's softgoods products provide : support, immobilization, restraint and transfer/ambulation of the upper extremities, including the back, neck, clavicle, hips, abdomen, and torso.
PART NUMBER LIST **FR:** LISTE DE REFERENCES **DE:** LISTE DER TEILENUMMERN **ES:** LISTA DE NÚMEROS DE PIEZAS	Master data list for TF-DJO-011-C
MDR RISK CLASSIFICATION **FR:** CLASSIFICATION DES RISQUES DU REGLEMENT MDR **DE:** MDR-RISIKOKLASSIFIZIERUNG **ES:** CLASIFICACIÓN DE RIESGOS DEL INFORME DE DISPOSITIVO MÉDICO (MDR)	Class I, Rule I
RED CLASSIFICATION **FR:** CLASSIFICATION RED **DE:** RED-KLASSIFIZIERUNG **ES:** CLASIFICACIÓN ROJA	N/A
CONFORMITY ASSESSMENT ROUTE **FR:** VOIE D'EVALUATION DE LA CONFORMITE **DE:** WEG DER KONFORMITÄTSBEWERTUNG **ES:** RUTA DE EVALUACIÓN DE CONFORMIDAD	Procedure set out in Article 19, Annex II and Annex III.
GMDN(s)	See master data
EMDN(s)	See master data
BASIC UDI-DI	See master data

DECLARATION OF CONFORMITY **FR:** DÉCLARATION DE CONFORMITÉ **DE:** KONFORMITÄTSERKLÄRUNG **ES:** DECLARACIÓN DE CONFORMIDAD	
THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF DJO, LLC. WE HEREBY DECLARE THAT THE MEDICAL DEVICE(S) SPECIFIED ABOVE MEET THE PROVISION OF THE REGULATION (EU) MDR 2017/745 FOR MEDICAL DEVICES AND DIRECTIVE 2011/65/EU ROHS 2. THIS DECLARATION IS SUPPORTED BY THE QUALITY SYSTEM APPROVAL TO ISO 13485. **FR:** CETTE DECLARATION DE CONFORMITE EST PUBLIEE SOUS LA SEULE RESPONSABILITE DE DJO, LLC. NOUS DECLARONS PAR LA PRESENTE QUE LE(S) DISPOSITIF(S) MEDICAL(AUX) SPECIFIE(S) CI-DESSUS REPOND(ENT) AUX DISPOSITIONS DU REGLEMENT (UE) MDR 2017/745 CONCERNANT LES DISPOSITIFS MEDICAUX. CETTE DECLARATION EST ETAYEE PAR L'APPROBATION DU SYSTEME QUALITE DE LA NORME ISO 13485. **DE:** DIESE KONFORMITÄTSERKLÄRUNG WIRD UNTER DER ALLEINIGEN VERANTWORTUNG VON DJO, LLC AUSGESTELLT. HIERMIT ERKLÄREN WIR, DASS DAS/DIE OBEN ANGEGEBENE(N) MEDIZINPRODUKT(E) DEN BESTIMMUNGEN DER VERORDNUNG (EU) MDR 2017/745 FÜR MEDIZINPRODUKTE ENTSPRICHT BZW. ENTSPRECHEN. DIESE ERKLÄRUNG WIRD DURCH DIE ZULASSUNG DES QUALITÄTSSYSTEMS NACH ISO 13485 UNTERSTÜTZT. **ES:** ESTA DECLARACION DE CONFORMIDAD SE EMITE BAJO LA RESPONSABILIDAD EXCLUSIVA DE DJO, LLC. POR LA PRESENTE DECLARAMOS QUE LOS DISPOSITIVOS MÉDICOS ESPECIFICADOS ANTERIORMENTE CUMPLEN CON LA DISPOSICIÓN DEL REGLAMENTO (UE) MDR 2017/745 PARA DISPOSITIVOS MÉDICOS. ESTA DECLARACIÓN ESTÁ RESPALDADA POR LA APROBACIÓN DE SISTEMA DE CALIDAD A ISO 13485.	
NOTIFIED BODY **FR:** ORGANISME NOTIFIE **DE:** BENANNTE STELLE **ES:** ORGANISMO NOTIFICADO	N/A
EC CERTIFICATE(S) **FR:** CERTIFICAT(S) CE **DE:** EG-ZERTIFIKAT(E) **ES:** CERTIFICADO(S) CE	N/A
PLACE OF ISSUE **FR:** LIEU DE DELIVRANCE **DE:** AUSSTELLUNGSORT **ES:** LUGAR DE EMISIÓN	DJO LLC Carlsbad, California, USA
APPROVAL SIGNATURE **FR:** SIGNATURE D'APPROBATION **DE:** UNTERSCHRIFT ZUR GENEHMIGUNG **ES:** FIRMA DE APROBACIÓN	**SIGNED FOR AND ON BEHALF OF DJO, LLC:** 
PRINTED NAME **FR:** NOM EN CARACTERES D'IMPRIMERIE **DE:** NAME IN DRUCKBUCHSTABEN **ES:** NOMBRE EN LETRA DE IMPRENTA	ALEXANDRA SCHWARZ
TITLE **FR:** TITRE **DE:** TITEL **ES:** TITULO	REGULATORY AFFAIRS MANAGER INTERNATIONAL
APPROVAL DATE **FR:** DATE D'APPROBATION **DE:** GENEHMIGUNGSDATUM **ES:** FECHA DE APROBACIÓN	APRIL 4, 2024