

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

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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 30 th , 2023
S	QMS-29285	DJO LLC SRN added	October 31 st , 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)	April 24 th , 2024
V	QMS-33518	Amended date following the amendment of Master data plan	October 30, 2024
Y	QMS-35352	Amended date following the amendment of Master data plan	February 26, 2025
YA	QMS-35988	Amended date following the amendment of Master data plan	March 28, 2025
YB	QMS-39828	Amended date following update of IFU 13- 00292 / DC-32650	January 8, 2026
YC	QMS-40100	Amended date following the amendment of Master data plan and changed IFU by DC- 32675	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 Rev. S
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'ÉVALUATION DE LA CONFORMITE DE: WEG DER KONFORMITÄTBEWERTUNG 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	
<p>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.</p> <p>FR: CETTE DÉCLARATION DE CONFORMITÉ EST PUBLIÉE SOUS LA SEULE RESPONSABILITÉ DE DJO, LLC. NOUS DÉCLARONS PAR LA PRÉSENTE QUE LE(S) DISPOSITIF(S) MÉDICAL(AUX) SPÉCIFIÉ(S) CI-DESSUS RÉPOND(ENT) AUX DISPOSITIONS DU RÈGLEMENT (UE) MDR 2017/745 CONCERNANT LES DISPOSITIFS MÉDICAUX. CETTE DÉCLARATION EST ÉTAYÉE PAR L'APPROBATION DU SYSTÈME QUALITÉ DE LA NORME ISO 13485.</p> <p>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.</p> <p>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.</p>	
NOTIFIED BODY FR: ORGANISME NOTIFIÉ DE: BENANNT 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: AUSSTELLUNGORT 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 CARACTÈRES D'IMPRIMERIE DE: NAME IN DRUCKBUCHSTABEN ES: NOMBRE EN LETRA DE IMPRENTA	ALEXANDRA RUF-SCHWARZ
TITLE FR: TITRE DE: TITEL ES: TÍTULO	REGULATORY AFFAIRS MANAGER INTERNATIONAL
APPROVAL DATE FR: DATE D'APPROBATION DE: GENEHMIGUNGSDATUM ES: FECHA DE APROBACIÓN	JANUARY 12, 2026