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-DRC-001
DESCRIPTION: **FR:** DESCRIPTION : **DE:** BESCHREIBUNG: **ES:** DESCRIPCIÓN:	Dr. Comfort Shoes
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
G	QMS-17610	Release of new MDR compliant DoC template, total re-write	04/01/2021
H	QMS-25136	Update of DOC following Master Plan update (related to the QMS-20912) Addition of intended use & EMDN, removal of UMDN (not required anymore), making reference to DOC new template release 1000.020 Rev F/ QMS-22301	02/29/2022
J	QMS-25871	Amended to add SRN for authorized representative, add to rule to risk classification, clarification of conformity assessment, general formatting, address change to sea otter place	December 15th, 2022
K	QMS-33518	Amended date and RA manager following the amendment of Master data plan	October 30th, 2024
L	QMS-36181	Added DJO LLC SRN, amended date and RA manager following the amendment of Master data plan	March 27th, 2025
M	QMS-37743	amended date and RA manager following the amendment of Master data plan	See agile

DECLARATION OF CONFORMITY **FR:** DECLARATION DE CONFORMITE **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:** REPRESENTANT AGREE POUR L'UNION EUROPEENNE **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	Dr. Comfort Shoes
INTENDED USE **FR:** UTILISATION PREVUE **DE:** ZWECKBESTIMMUNG **ES:** FINALIDAD PREVISTA	Dr. Comfort diabetic shoes with inserts are intended for people with diabetes by providing support and protection of diabetes foot ulcers. Dr Comfort Flex-OA shoes are intended to help people with knee osteoarthritis by providing support and stabilization.
PART NUMBER LIST **FR:** LISTE DE REFERENCES **DE:** LISTE DER TEILENUMMERN **ES:** LISTA DE NÚMEROS DE PIEZAS	TF-DRC-001-Master-Data Rev. H
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: DECLARATION DE CONFORMITE

DE: KONFORMITÄTSERKLÄRUNG

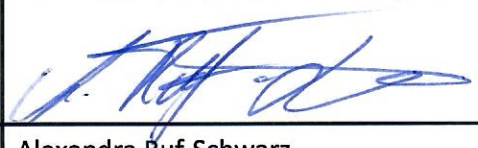
ES: DECLARACIÓN DE CONFORMIDAD

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 Ruf-Schwarz
TITLE **FR:** TITRE **DE:** TITEL **ES:** TITULO	Manager Regulatory Affairs International
APPROVAL DATE **FR:** DATE D'APPROBATION **DE:** GENEHMIGUNGSDATUM **ES:** FECHA DE APROBACIÓN	JULY 31ST, 2025