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| <b>UNDER MDR 2017/745: DECLARATION OF CONFORMITY</b><br><b>FR: EN VERTU DU MDR 2017/745 : DECLARATION DE CONFORMITE</b><br><b>DE: GEMÄß MDR 2017/745: KONFORMITÄTSERLÄRUNG</b><br><b>ES: SEGUN MDR 2017/745: DECLARACION DE CONFORMIDAD</b> |                               |
| <b>FOR TECHNICAL FILE:</b><br><b>FR: POUR LA FICHE TECHNIQUE :</b><br><b>DE: FÜR TECHNISCHE UNTERLAGEN:</b><br><b>ES: PARA EL ARCHIVO TÉCNICO:</b>                                                                                          | TF-DJO-011-B                  |
| <b>DESCRIPTION:</b><br><b>FR: DESCRIPTION :</b><br><b>DE: BESCHREIBUNG:</b><br><b>ES: DESCRIPCIÓN:</b>                                                                                                                                      | SOFTGOODS – LOWER EXTREMITIES |
| <b>RISK CLASSIFICATION:</b><br><b>FR: CLASSIFICATION DES RISQUES :</b><br><b>DE: RISIKOKLASSIFIZIERUNG:</b><br><b>ES: CLASIFICACIÓN DE RIESGOS:</b>                                                                                         | Class I                       |

| REVISION<br>FR: REVISION<br>DE: REVISION<br>ES: REVISION | CHANGE NO.<br>N° DE MODIFICATION<br>ÄNDERUNGSNR.<br>N.° DE CAMBIO | DESCRIPTION<br>DESCRIPTION<br>BESCHREIBUNG<br>DESCRIPCIÓN                                                                                                          | DATE<br>DATE<br>DATUM<br>FECHA    |
|----------------------------------------------------------|-------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| W                                                        | QMS-17382                                                         | Release of new MDR compliant DoC template, total re-write                                                                                                          | March 31 <sup>st</sup> , 2021     |
| Y                                                        | QMS-18844                                                         | Re-issue on current template to include Aircast Actyfoot and Airfree devices (PRO-152)                                                                             | September 27 <sup>th</sup> , 2021 |
| YA                                                       | QMS-22425                                                         | Added new GMDN numbers update of address                                                                                                                           | April 20 <sup>th</sup> , 2022     |
| YB                                                       | QMS-23891                                                         | Update conformity assessment route                                                                                                                                 | July 18 <sup>th</sup> , 2022      |
| YC                                                       | QMS-25138                                                         | Update of the master data plan<br>Addition of intended use & EMDN, removal of UMDN (not required anymore), making reference to DOC new template release/ QMS-22301 | November 04 <sup>th</sup> , 2022  |
| YD                                                       | QMS-25666                                                         | Update of the master data plan, addition of SRN                                                                                                                    | January 6 <sup>th</sup> , 2023    |
| YE                                                       | QMS-26528                                                         | Addition of Hand Written signature                                                                                                                                 | February 21 <sup>st</sup> , 2023  |
| YF                                                       | QMS-27335                                                         | Updated following the addition of new sku in the technical documentation & added the SRN for DJO LLC.                                                              | June 13 <sup>th</sup> , 2023      |
| YG                                                       | QMS-29285                                                         | Update of the TF-DJO-011-B summary and master data plan                                                                                                            | October 31, 2023                  |
| YH                                                       | QMS-30388                                                         | Updated following the addition of new sku in the technical documentation                                                                                           | January 17 <sup>th</sup> , 2024   |
| YJ                                                       | QMS-31626                                                         | Updated following the addition of new sku in the technical documentation                                                                                           | April 24 <sup>th</sup> , 2024     |
| YK                                                       | QMS-33518                                                         | Amended date following the amendment of Master data plan                                                                                                           | See agile                         |

| REVISION                                                                                                                                                                                                        | CHANGE NO.                                                                                                            | DESCRIPTION  | DATE  |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|--------------|-------|
| FR: REVISION                                                                                                                                                                                                    | N° DE MODIFICATION                                                                                                    | DESCRIPTION  | DATE  |
| DE: REVISION                                                                                                                                                                                                    | ÄNDERUNGSNR.                                                                                                          | BESCHREIBUNG | DATUM |
| ES: REVISION                                                                                                                                                                                                    | N.º DE CAMBIO                                                                                                         | DESCRIPCIÓN  | FECHA |
| <b>DECLARATION OF CONFORMITY</b><br><b>FR: DECLARATION DE CONFORMITE</b><br><b>DE: KONFORMITÄTSEKLRUNG</b><br><b>ES: DECLARACIÓN DE CONFORMIDAD</b>                                                             |                                                                                                                       |              |       |
| <b>MANUFACTURER</b><br><b>FR: FABRICANT</b><br><b>DE: HERSTELLER</b><br><b>ES: FABRICANTE</b>                                                                                                                   | DJO, LLC<br>5919 Sea Otter Place<br>Suite 200<br>Carlsbad, CA 92010<br>USA                                            |              |       |
| <b>SRN</b>                                                                                                                                                                                                      | US-MF-000034062                                                                                                       |              |       |
| <b>EU AUTHORIZED REPRESENTATIVE</b><br><b>FR: REPRESENTANT AGREE POUR L'UNION EUROPEENNE</b><br><b>DE: AUTORISIERTER VERTRETER IN DER EU</b><br><b>ES: REPRESENTANTE AUTORIZADO EN LA UE</b>                    | MDSS GmbH<br>Schiffgraben 41<br>30175 Hannover<br>Germany                                                             |              |       |
| <b>SRN</b>                                                                                                                                                                                                      | DE-AR-000005430                                                                                                       |              |       |
| <b>PRODUCT</b><br><b>FR: PRODUIT</b><br><b>DE: PRODUKT</b><br><b>ES: PRODUCTO</b>                                                                                                                               | SOFTGOODS – LOWER EXTREMITIES                                                                                         |              |       |
| <b>INTENDED USE</b><br><b>FR: UTILISATION PREVUE</b><br><b>DE: ZWECKBESTIMMUNG</b><br><b>ES: FINALIDAD PREVISTA</b>                                                                                             | Support, comfort, compression, and immobilization of the lower extremities, including the thigh, knee, ankle and foot |              |       |
| <b>PART NUMBER LIST</b><br><b>FR: LISTE DE REFERENCES</b><br><b>DE: LISTE DER TEILENUMMERN</b><br><b>ES: LISTA DE NÚMEROS DE PIEZAS</b>                                                                         | TF-DJO-011-B-Master-Data                                                                                              |              |       |
| <b>MDR RISK CLASSIFICATION</b><br><b>FR: CLASSIFICATION DES RISQUES DU REGLEMENT MDR</b><br><b>DE: MDR-RISIKOKLASSIFIZIERUNG</b><br><b>ES: CLASIFICACIÓN DE RIESGOS DEL INFORME DE DISPOSITIVO MÉDICO (MDR)</b> | Class I                                                                                                               |              |       |
| <b>RED CLASSIFICATION</b><br><b>FR: CLASSIFICATION RED</b><br><b>DE: RED-KLASSIFIZIERUNG</b><br><b>ES: CLASIFICACIÓN ROJA</b>                                                                                   | N/A                                                                                                                   |              |       |
| <b>CONFORMITY ASSESSMENT ROUTE</b><br><b>FR: VOIE D'ÉVALUATION DE LA CONFORMITE</b><br><b>DE: WEG DER KONFORMITÄTBEWERTUNG</b><br><b>ES: RUTA DE EVALUACIÓN DE CONFORMIDAD</b>                                  | The procedure set out in Article 19, Annex II and Annex III.                                                          |              |       |
| <b>GMDN(s)</b>                                                                                                                                                                                                  | See TF-DJO-011-B-Master-Data                                                                                          |              |       |
| <b>EMDN(s)</b>                                                                                                                                                                                                  | See TF-DJO-011-B-Master-Data                                                                                          |              |       |

| REVISION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | CHANGE NO.         | DESCRIPTION                                                                          | DATE  |
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| FR: REVISION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | N° DE MODIFICATION | DESCRIPTION                                                                          | DATE  |
| DE: REVISION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | ÄNDERUNGSNR.       | BESCHREIBUNG                                                                         | DATUM |
| ES: REVISION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | N.° DE CAMBIO      | DESCRIPCIÓN                                                                          | FECHA |
| <b>BASIC UDI-DI</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                    | See TF-DJO-011-B-Master-Data                                                         |       |
| <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. THIS DECLARATION IS SUPPORTED BY THE QUALITY SYSTEM CERTIFICATION TO ISO 13485.</p> <p><b>FR:</b> 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 CERTIFICATION DU SYSTEME QUALITE DE LA NORME ISO 13485.</p> <p><b>DE:</b> DIESE KONFORMITÄTSEKLRUNG WIRD UNTER DER ALLEINIGEN VERANTWORTUNG VON DJO, LLC AUSGESTELLT. HIERMIT ERKLÄREN WIR, DASS DAS/DIE OBEN ANGEGBENE(N) MEDIZINPRODUKT(E) DEN BESTIMMUNGEN DER VERORDNUNG (EU) MDR 2017/745 FÜR MEDIZINPRODUKTE ENTSPRICHT BZW. ENTSPRECHEN. DIESE ERKLÄRUNG WIRD DURCH DIE ZERTIFIZIERUNG DES QUALITÄTSSYSTEMS NACH ISO 13485 UNTERSTÜTZT.</p> <p><b>ES:</b> 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 CERTIFICACIÓN DE SISTEMA DE CALIDAD A ISO 13485.</p> |                    |                                                                                      |       |
| <b>NOTIFIED BODY</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                    | N/A                                                                                  |       |
| FR: ORGANISME NOTIFIE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                    |                                                                                      |       |
| DE: BENANNT STELLE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                    |                                                                                      |       |
| ES: ORGANISMO NOTIFICADO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                    |                                                                                      |       |
| <b>EC CERTIFICATE(S)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                    | N/A                                                                                  |       |
| FR: CERTIFICAT(S) CE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                    |                                                                                      |       |
| DE: EG-ZERTIFIKAT(E)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                    |                                                                                      |       |
| ES: CERTIFICADO(S) CE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                    |                                                                                      |       |
| <b>PLACE OF ISSUE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                    | DJO LLC Carlsbad, California, USA                                                    |       |
| FR: LIEU DE DELIVRANCE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                    |                                                                                      |       |
| DE: AUSSTELLUNGSTORT                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                    |                                                                                      |       |
| ES: LUGAR DE EMISIÓN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                    |                                                                                      |       |
| <b>APPROVAL SIGNATURE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                    | <b>SIGNED FOR AND ON BEHALF OF DJO, LLC:</b>                                         |       |
| FR: SIGNATURE D'APPROBATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                    |  |       |
| DE: UNTERSCHRIFT ZUR GENEHMIGUNG                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                    |                                                                                      |       |
| ES: FIRMA DE APROBACIÓN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                    |                                                                                      |       |
| <b>PRINTED NAME</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                    | Alexandra Schwarz                                                                    |       |
| FR: NOM EN CARACTERES D'IMPRIMERIE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                    |                                                                                      |       |
| DE: NAME IN DRUCKBUCHSTABEN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                    |                                                                                      |       |
| ES: NOMBRE EN LETRA DE IMPRENTA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                    |                                                                                      |       |
| <b>TITLE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                    | Regulatory Affairs Manager International                                             |       |
| FR: TITRE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                    |                                                                                      |       |
| DE: TITEL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                    |                                                                                      |       |
| ES: TÍTULO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                    |                                                                                      |       |
| <b>APPROVAL DATE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                    | OCTOBER 14TH, 2024                                                                   |       |
| FR: DATE D'APPROBATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                    |                                                                                      |       |
| DE: GENEHMIGUNGSDATUM                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                    |                                                                                      |       |
| ES: FECHA DE APROBACION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                    |                                                                                      |       |