



MDR TECHNICAL FILE – DECLARATION OF CONFORMITY

DESCRIPTION	Softgoods Head and Body
CLASSIFICATION	Class I

Revision	Effective Date	Originator	Description
A	08/01/2013	L.Trotter	Separate DOC from Tech File Rev control as attachment to simplify document updates. Additions of GMDNS and UMDNS codes
B	01/24/2014	S.Ethington	Updated signatory to be Jeff Monroe Senior Manager Global Quality Systems
C	6/26/2015	J.Beasley	Revised tech file and update DOC to reflect Mark Stavro, Senior Director Global Regulatory Affairs, include Usability Standard as applicable, etc.
D	1/26/2016	R.Daoud	Updated GMDNS and UMDNS codes.
E	8/10/2016	V.Khoshnevis	Adding Consumer's Bionic Back Wrap No change to GMDNs or UMDNs codes
F	7/26/2018	L. Mullens	QMS-07875 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.
G	17 Jan 2019	D.Hunter	Updated signatory; Updated standards to current revisions; Delete "as amended up to" portion of the "All relevant provisions" statement.
H	29 May 2020	B Dombovari / T Allard	QMS-13368 Obsolete products removed Update to include TENS Lumbar Belt, Powerstrap Lumbar Belt, C2+ and MyBabystrap products
J	See Agile	T Allard	Transfer of information into new MDR template, total re-write.
K	See Agile	M Davis	QMS-18303: Update to align with revision of TF-DJO-011-C-MASTER-DATA, which includes Isoform Group 2 back braces.

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
PRODUCT	SOFTGOODS - HEAD AND BODY
PART NUMBER LIST	Master data list for TF-DJO-011-C
MDR CLASSIFICATION RED CLASSIFICATION	Class I No Radio Emissions
CONFORMITY ASSESSMENT ROUTE	Annex VII (MDR)
GMDN CODE	13356, 13673, 13810, 31724, 33031, 35409, 36228, 40538, 41025, 41029, 41039, 41057, 41442, 44848, 45606, 47217, 36228, 44851
UMDNS CODE	10-003, 10-284, 11-093, 13-346, 13-810, 14-169, 11-657, 17-859, 15-557, 17909
BASIC UDI-DI	Master data list for TF-DJO-011-C
SRN NUMBER	TBN
THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF DJO, LLC. WE HEREBY DECLARE THAT HE MEDICAL DEVICE(S) SPECIFIED ABOVE MEET THE PROVISION OF THE REGULATION (EU) MDR 2017/745 FOR MEDICAL DEVICES. THIS DECLARATION IS SUPPORTED BY THE QUALITY SYSTEM APPROVAL TO ISO 13485.	
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, USA
SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO, LLC  _____ Name: Michael Davis Title: Regulatory Affairs Consultant (BAS) Date: September 7, 2021