TECHNICAL FILE – DECLARATION OF CONFORMITY

DESCRIPTION	CCMI Rigid Bracing and Accessories with Measure
CLASSIFICATION	Class I, Measuring

Revision	Effective Date	Originator	Description
A	12 Dec 2014	P. Bounaud	Initial Release
B	27 February 2017	W.Fisher	Update EC Certificate Information
C	See Agile	S. Rimer	Update EC Cert – Renewed / Consolidated EC Certificates. Update of referenced standards and other related information.

DECLARATION OF CONFORMITY

MANUFACTURER	DJO, LLC 1430 Decision Street Vista, CA 92081-8553 U.S.A.
EU AUTHORIZED REPRESENTATIVE	MDSS GmbH Schiffgraben 41 30175 Hannover Germany
PRODUCT	CCMI MARK III REPLACEMENT TAPE MODULE
CLASSIFICATION	Class I (Measuring Device)
CONFORMITY ASSESSMENT ROUTE	Annex II (MDD) – Those aspects of Annex-II concerned with the metrological requirements of a Class-I - Measuring Device
GMDN CODE	48157 37743
UMDNS CODE	23-766

WE, THE MANUFACTURER, DJO LLC., DECLARE UNDER SOLE RESPONSIBILITY THAT THE ITEM TO WHICH THIS DECLARATION IS RELATED IS IN CONFORMITY WITH:

- ALL RELEVANT PROVISIONS OUTLINED IN THE OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITY COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES. THE ITEM COMPLIES WITH ALL RELEVANT PROVISIONS OF THE ANNEX I ESSENTIAL REQUIREMENTS, AS RELAVENT TO ANNEX-V AND ANNEX-VII, AS AMENDED UP TO AND INCLUSIVE OF COUNCIL DIRECTIVE 2007/47/EC.
- DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 8 JUNE 2011 ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (ROHS-2)

STANDARDS APPLIED	ISO 13485:2016	Medical Devices – Quality management system – Requirements for regulatory purposes
	EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
	EN 1041:2008 + A1:2013	Information supplied by the manufacturer with medical devices
	ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
	ISO 10993-1:2018	Biological Evaluation of medical devices – Part 1: General requirements for basic safety and essential performance
	IEC 62366:2014	Medical Devices - Application of usability engineering to medical Devices
	MEDDEV 2.7.1 Rev 4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
	Uniform Freight Classification Rule 41 / National Motor Freight Classification Item 222	Shipping Regulations
NOTIFIED BODY	**BSI Group** Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands Tel: + 31 20 346 0780 **No: 2797**	
EC CERTIFICATE(S)	EC Certificate #: CE 678711 Initial Certification Date: 2018-07-20 Certificate Effective Date: 2019-12-12 Certificate Expiration Date: 2024-05-26	
PLACE OF ISSUE	Vista, CA, USA	

SIGNATURE	SIGNED FOR AND ON BEHALF OF DJO, LLC.: Name: Jim Pomeroy Title: VP, Global Quality Assurance and Regulatory Affairs Date: 2019-12-12