By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

DJO FRANCE SAS
Centre Européen de Frêt
3 rue de Bethar
Mouguerre
64990
France

Facility ID Number: F000514

Holds Certificate No: **MDSAP 695371**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-07-18 Effective Date: 2023-08-30 Expiry Date: 2024-05-21

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.

Digitally signed by Prodan Sveatoslav
Date: 2023.11.24 10:55:34 EET
Reason: MoldSign Signature
Location: Moldova

Certificate No: **MDSAP 695371**

Registered Scope:

Design, manufacture, distribution and service of Radial Pressure Wave devices, Neuromuscular stimulators, Ultrasound units and their software.

Design, manufacture and distribution of Iontophoresis system electrodes and non-sterile accessories.

Distribution of orthopaedic units and diathermy units.

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