EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 681250**

Issued To: **DJO FRANCE SAS**
Centre Européen de Frêt
3 rue de Bethar
Mouguerre
64990
France

In respect of:

Design and manufacture of Radial Pressure Wave devices, Neuromuscular stimulators, Ultrasound units, Therapeutic lasers and non-sterile accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President - Medical Devices

First Issued: **2018-07-27** Date: **2020-09-22** Expiry Date: **2024-01-23**

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Supplementary Information to CE 681250

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIb		
46571 11248 46571 37794 35147	Intelect Neo Clinical Therapy System	**sEMG & STIM INDICATIONS**: Stroke rehab by muscle re-education, Relaxation of muscle spasms, Prevention or retardation of disuse atrophy, Increase local blood circulation, Muscle re-education, Maintaining or increasing range of motion. **Indications for EMG alone**: To determine the activation timing of muscles for retraining of muscle activation, coordinating of muscle activation and any indication of the force produced by muscle for control and maintenance of muscle contractions for relaxation muscle training and muscle re-education. Indications for Incontinence: Provide biofeedback for the purpose of rehabilitation of pelvic floor muscles for the treatment of urinary Incontinence. **Ultrasound**: Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions. **Laser**: To provide topical heating for increasing local blood circulation, relieving minor muscle and joint aches, pains, and stiffness, relaxing muscles, relieving muscle spasms, relieving minor pain and stiffness associated with arthritis, promoting nerve regeneration, bone growth, and ligament repair and healing wounds.

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Number	Device Name	Intended purpose per IFU
Class IIb		
60409	Intelect High Power Lasers (HPL7 & HPL15)	Sub-acromial conflicts, cuff injuries, Arthrosis, Epicondylitisi, Eqitorcleitis, Epitrocleitis, Bursitis, Fracture aftereffects, Tendinitis, Carpal tunnel syndrome, Pubalgia, Gonarthrosis, Reconstruction of anterior cruciate ligament, Crow's foot Bursitis, Sprains, Plantar faciitis, Achiles tendon, Cervicalgia, Cervical brachialgia, Contracture, Spondylosis, Lumbago, Coxarthrosis, Piriformis syndrome, Sciatica
Class IIa		
MD 1103	Accessories for Ultrasound and Electrotherapy	-
MD 1103	Transcutaneous Nerve Stimulators	-
MD 1103	Neuromuscular Stimulators	-
MD 1103	Radial Pressure Wave Devices	-

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1103 MD 1402	Simulator for Neuromuscular, Transcutaneous Nerve and ultrasound physical therapy	-

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Issued To:	**DJO FRANCE SAS** **Centre Européen de Frêt** **3 rue de Bethar** **Mouguerre** **64990** **France**

Subcontractor:	**Service(s) supplied**
dj Orthopedics de Mexico S.A de C.V Carretera Libre Tijuana Tecate # 20230 Parque Industrial EI Florido Tijuana B.C CP22244 Mexico	**Manufacture**
DJO Tunisie Zone Industrielle Pudriere I Rue 13 Aout Sfax 3002 Tunisia	**Manufacture**
DJO, LLC 1430 Decision Street Vista California 92081 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Domex Technology Corporation No. 6, Hsin-Ann Rd., Hsinchu Science Park Hsinchu 30078 Taiwan	**Manufacture**
Fujidynamics DT Ltd No. A46, Gao Yu South Road Ping Shan Tangxia Town Dongguan City Guang Dong Province P.R. China	**Manufacture**
Mectronic Medicale S.r.l Via Orio Al Serio 15 Grassobbio Bergamo 24050 Italy	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Medireha GmbH Am Laidholzle 2 UMKIRCH 79224 Germany	**Manufacture**
Moulage Electronique Mecanique Le Bois du May Chevillonsur-Huillard 45700 France	**Manufacture**
OnCore Manufacturing LLC dba NEO Tech 237 Via Vera Cruz San Marcos CA 92078 United States of America	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Process Parc d'Activites des Ecobuts, 2 Chemin des Halles Challans 85300 France	**Manufacture**
SOUTH DAKOTA PARTNERS, INC. 205 Highway 22 East Clear Lake South Dakota 57226 USA	**Manufacture**
Storz Medical AG Lohstampfestrasse 8 8274 Tägerwilen Switzerland	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
27 July 2018	8801381	First issue. Transfer from another Notified Body.
23 January 2019	9689506	Renewal. Corrected DJO Tunisie address.
26 February 2019	9628289	Traceable to NB 0086.
22 September 2020	3202982	Addition of subcontractor 'Storz Medical AG' for manufacture. Updated the device table to add class IIa device,'Simulator for Neuromuscular ,Transcutaneous Nerve and ultrasound physical therapy'.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
23 February 2022	3635040	Addition of subcontractor OnCore Manufacturing LLC dba NEO Tech, 237 Via Vera Cruz, San Marcos, CA 92078, USA

Inspiring trust for a more resilient world.

23 February 2022

DJO FRANCE SAS
Centre Européen de Frêt
3 rue de Bethar
Mouguerre
64990
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 681250	93/42/EEC Annex II excluding Section 4	3635040	Addition of subcontractor OnCore Manufacturing LLC dba NEO Tech, 237 Via Vera Cruz, San Marcos, CA 92078, USA

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

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