

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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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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	<p>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.</p> <p>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.</p> <p>Ultrasound: Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions.</p> <p>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.</p>

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Number	Device Name	Intended purpose per IFU
Class IIb		
60409	Intellect High Power Lasers (HPL7 & HPL15)	Sub-acromial conflicts, cuff injuries, Arthrosis, Epicondylitis, Eptorcleitis, Epitrocleitis, Bursitis, Fracture aftereffects, Tendinitis, Carpal tunnel syndrome, Pubalgia, Gonarthrosis, Reconstruction of anterior cruciate ligament, Crow's foot Bursitis, Sprains, Plantar faciitis, Achilles 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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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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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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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
Process Parc d'Activites des Ecobuts, 2 Chemin des Halles Challans 85300 France	Manufacture

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Subcontractor:

Service(s) supplied

SOUTH DAKOTA PARTNERS, INC.
 205 Highway 22
 East Clear Lake
 South Dakota
 57226
 USA

Manufacture

Storz Medical AG
 Lohstampfstrasse 8
 8274 Tägerwilen
 Switzerland

Manufacture

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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.
Current	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'.

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