By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 678711**

Issued To: **DJO, LLC**
5919 Sea Otter Place
Suite 200
Carlsbad
California
92010
USA

In respect of:

See certificate scope page.

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: **2018-07-20** Date: **2021-05-24** Expiry Date: **2024-05-26**

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Certificate No: CE 678711

Certificate Scope:

Design and manufacture of Neuromuscular stimulators, and re-circulating Cold Therapy devices for pain management and rehabilitation, Bone growth stimulators, Therapeutic compression devices, Powered traction units, Transcutaneous nerve stimulators, Ultrasound units, Therapeutic lasers and non-sterile accessories.
Those aspects of Annex II concerned with the metrological requirements of leg contouring measuring devices and angle reference bending tools.
Those aspects of Annex II concerned with securing and maintaining sterile conditions of a component part of the VenaFLow System for the treatment of DVT (Deep Vein Thrombosis), sterile cold therapy pads and sterile quantum surgical drape.

First Issued: **2018-07-20** Date: **2021-05-24** Expiry Date: **2024-05-26**

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Supplementary Information to CE 678711

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Number	Device Name	Intended purpose per IFU
Class IIb		
NBOG MD 1103 NBOG MD 1402 NBOG MD 1301	NMES, TENS, Laser	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.

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Number	Device Name	Intended purpose per IFU
		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		
NBOG MD 1402	Therapeutic Laser Applicators	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, healing wounds
Class IIa		
NBOG MD 1103	TENS and NMES devices	N/A
NBOG MD 1103	Re-circulating Cold Therapy devices	N/A
NBOG MD 1103	Traction and Decompression Therapy Systems	N/A
NBOG MD 1103	VitalStim and VitalStim Plus Neuromuscular Stimulators	N/A
NBOG MD 1103	Bone Growth Stimulators	N/A
NBOG MD 1103	TENS Stimulator: Ormed Select, Direct TENS	N/A

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Number	Device Name	Intended purpose per IFU
NBOG MD 1103	Intermittent Pneumatic Compression Devices VenaFlow & VenaFlow Elite, VenaPro	N/A
NBOG MD 1402	Therapeutic Laser Applicators	N/A
NBOG MD 1402	Ultrasound Applicators	N/A
Class I sterile		
NBOG MD 0103	VenaFlow Intermittent Pneumatic Compression Sterile Cuffs	N/A
NBOG MD 0103	Cold Therapy Pads	N/A
NBOG MD 0106	Quantum Surgical Drape	N/A
Class I measuring		
NBOG MD 0104	CCMI Rigid Bracing & Accessories	N/A

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

List of Significant Subcontractors

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

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Date:	**2021-05-24**
Issued To:	**DJO, LLC** **5919 Sea Otter Place** **Suite 200** **Carlsbad** **California** **92010** **USA**

Subcontractor:	**Service(s) supplied**
DJ Orthopedics de México, S.A. de C.V. Carretera Libre Tijuana Tecate #20230 Submetropoli El Florido Tijuana BC 22244 Mexico	**Manufacture**
DJO Global- Scott 3151 Scott Street Vista California 92081 USA	**Manufacture**
Domex Technology Corporation No. 6, Hsin-Ann Rd., Hsinchu Science Park Hsinchu 30078 Taiwan	**Manufacture**

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Subcontractor:	**Service(s) supplied**
MDSS GmbH Schiffgraben 41 Hannover 30175 Germany	**EU Representative**
SOUTH DAKOTA PARTNERS, INC. 205 Highway 22 East Clear Lake South Dakota 57226 USA	**Manufacture**
Sterigenics US LLC 344 Bonnie Circle Corona California 92880 USA	**Radiation (Gamma Sterilization)**

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Subcontractor:	**Service(s) supplied**
Verity Medical Ltd Unit 7, Upper Slackstead Farm Farley Lane Braishfield, Romsey Hampshire SO51 0QL United Kingdom	**Finished Device Supplier**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
20 July 2018	8780405	First issue. Transfer from another Notified Body.
01 March 2019	8861667	Traceable to NB 0086.
12 December 2019	9759679	Added "re-circulating Cold Therapy devices for pain management and rehabilitation," to certificate scope. Added "Those aspects of Annex II concerned with the metrological requirements of leg contouring measuring devices and angle reference bending tools" to certificate scope. Added "Those aspects of Annex II concerned with securing and maintaining sterile conditions of a component part of the VenaFLow System for the treatment of DVT (Deep Vein Thrombosis) and sterile cold therapy pads" to certificate scope. Added subcontractors Sterigenics US, LLC and Verity Medical Ltd. Changed subcontractor name from "Vista Manufacturing Center" to "DJO Global – Scott" to align with subcontractor's current ISO 13485 certification. Updated product information table. Renewal

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Date	Reference Number	Action
Current	3446995	Addition of "sterile quantum surgical drape" to the scope of the certificate. Address change from "1430 Decision Street, Vista, California, 92081, USA" to "5919 Sea Otter Place, Suite 200, Carlsbad, California, 92010, USA"