

# 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  
1430 Decision Street  
Vista  
California  
92081  
USA**

In respect of:

**Design and manufacture of Neuromuscular stimulators, Bone growth stimulators, Therapeutic compression devices, Powered traction units, Transcutaneous nerve 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 0086):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2018-07-20**

Date: **2018-07-20**

Expiry Date: **2019-12-14**

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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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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:

Certificate No: **CE 678711**  
 Date: **2018-07-20**  
 Issued To: **DJO, LLC**  
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**Vista**  
**California**  
**92081**  
**USA**

### 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**

Domex Technology Corporation  
 No. 6, Hsin-Ann Rd.,  
 Hsinchu Science Park  
 Hsinchu  
 30078  
 Taiwan

**Manufacture**

MDSS GmbH  
 Schiffgraben 41  
 Hannover  
 30175  
 Germany

**EU Representative**

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**Vista**  
**California**  
**92081**  
**USA**

Subcontractor:	Service(s) supplied
SOUTH DAKOTA PARTNERS, INC. 205 Highway 22 East Clear Lake South Dakota 57226 USA	Manufacture
Vista Manufacturing Center 3151 Scott Street Vista California 92081 USA	Manufacture

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## Certificate History

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Date	Reference Number	Action
Current	8780405	First issue. Transfer from another Notified Body.

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