

# EC Certificate - Full Quality Assurance System

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

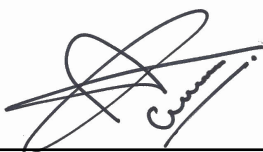
**No.** CE 665543  
**Issued To:** **JTECH Medical Industries, Inc**  
**7633 S Main**  
**Midvale**  
**Utah**  
**84047**  
**USA**

In respect of:

**Those aspects of Annex II relating to metrology in the design and manufacture of dynamometers, goniometers and instruments used in the assessment of physical strength and flexibility.**

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):



Albert Roossien, Regulatory Lead

First Issued: **2017-08-16**

Date: **2019-02-20**

Expiry Date: **2022-08-15**

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Page 1 of 1

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.

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.

A member of BSI Group of Companies.

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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**

Advena Ltd  
Tower Business Centre  
2nd Floor, Tower Street  
Swatar  
BKR 4013  
Malta

**EU Representative**

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 665543**  
 Date: **2019-02-20**  
 Issued To: **JTECH Medical Industries, Inc**  
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Date	Reference Number	Action
16 August 2017	8650658	First Issue.
21 February 2018	8874995	Correction to certificate address & change of EU Representative to Emergo Europe.
06 February 2019	9670046	Change of EU Representative from Emergo Europe to Advena Ltd.
Current	8877171	Traceable to NB 0086.

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Page 1 of 1

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