

EC Certificate - Full Quality Assurance System

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

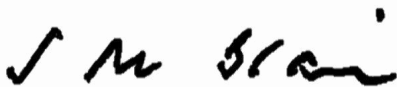
No. CE 665543
Issued To: **JTECH Medical Industries, Inc**
7633 Main Street
Midvale
Utah
84047
USA

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 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

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

Date: **2017-08-16**

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

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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:

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84047
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Subcontractor:

Service(s) supplied

Atlantico Systems
34 Oldfield
Kingston
Galway
Ireland

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

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84047
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| Date | Reference Number | Action |
|-------------|-------------------------|---------------|
| Current | 8650658 | First Issue. |

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