

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**No.****CE 669949**

Issued To:

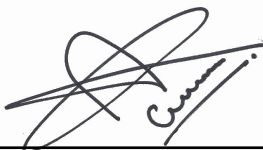
**Advanced Mechanical Technology, Inc.  
176 Waltham Street  
Watertown  
Massachusetts  
02472  
USA**

In respect of:

**Those aspects of Annex V related to metrology in the manufacture of Force Platform Systems for use in measuring forces in Gait and Balance for evaluation, therapeutic treatment planning and monitoring of treatment progress.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2018-01-22**Date: **2019-03-02**Expiry Date: **2023-01-21**

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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 V

## List of Significant Subcontractors

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

Certificate No: **CE 669949**  
Date: **2019-03-02**  
Issued To: **Advanced Mechanical Technology, Inc.  
176 Waltham Street  
Watertown  
Massachusetts  
02472  
USA**

**Subcontractor:**

**Service(s) supplied**

Emergo Europe  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

**EU Representative**

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# EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 669949**  
 Date: **2019-03-02**  
 Issued To: **Advanced Mechanical Technology, Inc.  
 176 Waltham Street  
 Watertown  
 Massachusetts  
 02472  
 USA**

Date	Reference Number	Action
21 January 2018	8696999	First Issue.
Current	8859169	Traceable to NB 0086.

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