

### **EC CERTIFICATION**

## FULL QUALITY ASSURANCE SYSTEM

#### Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

# Computer Sports Medicine, Inc.

Main Site: 101 Tosca Drive, Stoughton, MA 02072 - 1505, USA

#### **Product Category:**

- Isokinetic Testing/Exercise System

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:

41314604-02

**Initial Certification Date:** 

16 August 2004

Certificate Valid from:

21 August 2019

**Certificate Expiry Date:** 

27 May 2024



Accred. no. 1003 Certification of Management Systems ISO/IEC 17021-1

**Bob Andersson** 

Certification Authority MDD Intertek Semko AB, Kista, Sweden

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21 August 2019

**Signed Date** 

Intertek Semko AB Box 1103, SE-164 22 Kista, Sweden Telephone +46 8 750 00 00 medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.



