

## **CERTIFICATE**OF REGISTRATION

This is to certify that the management system of:

## Computer Sports Medicine, Inc. (CSMi)

(FIN F000782)

Main Site: 101 Tosca Drive

Stoughton, Massachusetts 02072-1505 United States

has been registered by Intertek, an MDSAP recognised auditing organisation, as conforming to the requirements of:

### ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

### The management system is applicable to:

Design, manufacture, service and installation of isokinetic and exercise systems.

**Certificate Number:** 

0074254-03

**Initial Certification Date:** 

2018-04-12

**Date of Certification Decision:** 

2024-03-25

**Certification Effective Date:** 

2024-04-11

**Certification Expiry Date:** 

2027-04-11





intertek

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc. 4700 Broadmoor SE, Suite 200 Kentwood, MI, USA, 49512







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**Certificate Number:** 

0167505

**Revision:** 

00

**Initial Certification Date:** 

12 April 2024

**Date of Certification Decision:** 

12 April 2024

**Certificate Valid Date:** 

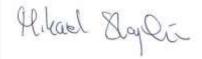
12 April 2024

**Certificate Expiry Date:** 

11 April 2027







#### Mikael Hagelin

Certification Authority, Intertek Medical Notified Body AB

Intertek Medical Notified Body AB P.O. Box 1103, SE-164 22 Kista, Sweden



