

CERTIFICATEOF 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





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