

EC CERTIFICATION

EU Quality Management System Certificate

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Computer Sports Medicine, Inc.

101 Tosca Drive Stoughton, Massachusetts 02072-1505 United States

Manufacturer SRN: US-MF-000037948

Authorised Representative Name

Emergo Europe B.V.

Westervoortsedijk , 60 6827 AT Arnhem, Netherlands

Scope:

Physiotherapy and rehabilitation instruments

Certificate Number:

28620211187

Revision:

00

Initial Certification Date:

22 April 2025

Certificate Decision Date:

22 April 2025

Certificate Issue Date:

22 April 2025

Certificate Expiry Date:

11 April 2030



Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.



PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	TD00354-001, HUMAC NORM
Audit Report Reference	Stage 1 audit ACTY-2023-635581
	Stage 2 audit ACTY-2023-635582
Change Notice Reference	

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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28620211187

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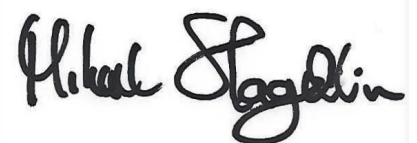
22 April 2025

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620211187	22 April 2025	Initial Certificate



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PRODUCT LIST FOR CERTIFICATE

Issued to:

Computer Sports Medicine, Inc.

Certificate number:

28620211187

Certificate valid from:

2025-04-22

Product List Issue Date:

22 April 2025

Product	Classification and EMDN	Intended use ¹	Date Added
Physiotherapy and rehabilitation instruments			
Basic UDI-DI: 08601390003502140VG			
502140 - HUMAC NORM	Class IIa V9099		2025-04-22



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¹The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

