

# 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.

31 Tosca Drive – Suite 1, Stoughton, Massachusetts 02072, 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:**  
01

**Initial Certification Date:**  
22 April 2025

**Certificate Decision Date:**  
08 May 2026

**Certificate Issue Date:**  
08 May 2026

**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	CN00354-007

**CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE**

None
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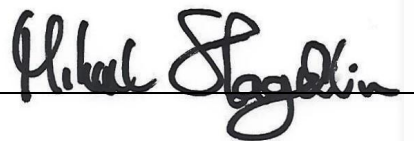
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**CERTIFICATE HISTORY**

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620211187	22 April 2025	Initial Certificate
28620211187-01	08 May 2026	Address change



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## PRODUCT LIST FOR CERTIFICATE

**Issued to:** Computer Sports Medicine, Inc.

**Certificate number:** 28620211187-01

**Certificate valid from:** 2026-05-08

**Product list issue date:**  
13 May 2026

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



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

