



101 Tosca Drive
Stoughton, MA 02072 USA
(Phone) 781.297-2034
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(Web) www.csmisolutions.com

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product Name	Model/Number
TEF Modular Component (TMC)	TMC / 7310A001

MANUFACTURER		
Name of Company	Address	Representative
Computer Sports Medicine, Inc.	101 Tosca Drive Stoughton, MA 02072 USA	Richard J. Potash

AUTHORIZED REPRESENTATIVE		
Name of Company	Address	Telephone/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

REGISTRATION INFORMATION	
Notified Body and ID #	EC Certificate number
Intertek Medical Notified Body AB, NB 2862 Box 1103, SE-164 22 Kista, Sweden Notified Body Number: 2862	41314604-02 NB Confirmation Letter CN00354-01

CONFORMITY ASSESSMENT		
Device Classification	Route to Compliance	Standards Applied
Class I according to rule I	Annex II of Council Directive 93/42/EEC	EN ISO 13485:2016

We hereby declare that the above-mentioned device complies with the Swedish legislation 1993:584 and LVFS 2003:11 transposing Council Directive 93/42/EEC concerning Medical Devices.

COMPANY REPRESENTATIVE: Richard J. Potash
TITLE: President

SIGNATURE: 

DATE: April 22, 2024



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PRODUCT IDENTIFICATION	
Product Name	Model/Number
HUMAC NORM Isokinetic Testing & Exercise System	HUMAC NORM / 502140

MANUFACTURER		
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Computer Sports Medicine, Inc.	101 Tosca Drive Stoughton, MA 02072 USA	Richard J. Potash

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CONFORMITY ASSESSMENT		
Device Classification	Route to Compliance	Standards Applied
Class IIa according to rule IX	Annex II of Council Directive 93/42/EEC	EN ISO 13485:2016

We hereby declare that the above-mentioned device complies with the Swedish legislation 1993:584 and LVFS 2003:11 transposing Council Directive 93/42/EEC concerning Medical Devices.

COMPANY REPRESENTATIVE: Richard J. Potash

TITLE: President

SIGNATURE:

DATE:

April 22, 2024