



CSMi CONFIDENTIAL
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Declaration of Conformity

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

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	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

REGISTRATION INFORMATION	
Notified Body and ID #	EC Certificate number
Semko CE0413	41314604-01

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: August 2, 2019