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Declaration of Conformity

MANUFACTURER		
Name of Company	Address	SRN
Computer Sports Medicine, Inc.	101 Tosca Drive Stoughton, MA 02072 USA	US-MF-000037948

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 europe@emergogroup.com

PRODUCT IDENTIFICATION	
Product Name	Code / Catalog Number
HUMAC NORM	502140
Intended Purpose	BASIC UDI-DI
The HUMAC NORM System is intended for physical therapy to exercise, measure, evaluate, and increase the strength and control of muscles, and increase the Range of Motion (ROM) of joints.	08601390003502140VG

RISK CLASS FOR DEVICE		
Device Classification		Common Specifications / Standards
Class:	Ila	EN ISO 13485:2016, IEC 60601-1:2005 Ed.3+A1;A2;C3, ES 60601-1:2005+A1;A2, IEC 60601-1-2:2014 Ed.4, IEC 60601-1-6:2010 Ed.3+A1;A2, IEC 60601-1-9:2007 Ed.1+A1;A2, CB Scheme, EN ISO 14971:2019, IEC62304:2006/A1:2016, ISO 15223-1:2021
Rule:	9	

NOTIFIED BODY		
Name of Company	ID Number	Certificate Reference(s)
Intertek Medical Notified Body AB, NB	2862	28620211187

ROUTE TO COMPLIANCE
MDR Annex IX Chapters 1 & 3

Computer Sports Medicine, Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745.
- Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive 2011/65/EU as amended by (EU) 2015/863.
- Machinery Directive 2006/42/EC.

COMPANY REPRESENTATIVE: Richard J. Potash

TITLE: CEO

SIGNATURE:



PLACE OF ISSUANCE:

STOUGHTON, MA USA

DATE:

26/04/2025