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Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Biodex Medical Systems, Inc	49 Natcon Dr Shirley, NY 11967, USA	US-MF-000028834

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 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Number**
System 4 PRO	850-000
Contains **MODEL NUMBER(s)** **850-000 System 4 Pro includes:** 850-000-E300 Dell CPU 850-109-J800 Software C07-015 Biodex Advantage Software Manual C08-051 Biodex Multi Joint System Installation Instructions C08-246 System 4 Multi-Joint System Poster C14113 HP Office Jet printer C12940 Touch Screen Monitor with Stand 900-860 Power head / Gimbal 830-000-K904 Limb Support Kit: 830-154 Arm / Leg Support 830-155 Foot Rest Tube 820-153 Small Tee Cap Screws (14 pieces) 945-300-M322 Levelers (6 pieces) 850-000-K900 PRO Attachments Kit: 830-157 Elbow / Shoulder Attachment 830-158 Wrist Attachment 830-174 Knee Attachment, Left 830-175 Knee Attachment, Right 830-321 Shoulder Attachment 830-332 Ankle Attachment 830-350 Calibration Weight 830-550 Hamstring 830-269 Work Sim Tools 830-260 Anti-Shear, Left 830-261 Anti-Shear, Right 830-315 Complete Hip Attachment 830-320-A000 Seat Back Brace Assembly 830-240 Attachment Rack 850-230-A000 Universal Pro Single Chair Assembly	

850-145-A000 Tee Base 835-210-A000 CDS Cart	
Intended Purpose	**Basic UDI-DI**
System 4 is intended to identify, treat, and document the physical impairments that cause functional limitations typical of sports injuries, orthopedics, pediatric medicine, and neurorehabilitation.	07181752014S

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	IIa	• **ISO 13485:2016** Medical devices -- Quality management systems -- Requirements for regulatory purposes • **ISO 14971: 2019** Medical devices -- Application of risk management to medical devices • **ISO 15223-1:2021** Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements • **ISO 7000:2019** Graphical symbols for use on equipment -- Registered symbols • **ISO 10993-1:2018** Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process • **IEC 62366-1:2015+AMD1:2020** CSV Consolidated version Medical devices - Part 1: Application of usability engineering to medical devices • **IEC 62304:2006+AMD1:2015** CSV Consolidated version Medical device software - Software life cycle processes • **IEC 60601-1 Ed. 3.2 en:2020** Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance • **ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]** Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)] • **CAN/CSA-C22.2 No. 60601-1:2014** • **IEC 60601-1-2:2014+AMD1:2020** CSV Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
Rule:	9	

NOTIFIED BODY			
Name of Company	**ID Number**	**Conformity Assessment Procedure**	**Certificate Reference(s)**
Intertek Semko AB	0413	Annex II MDD 93/42/EEC Council Directive (excluding Section 4)	41313009-03

QUALITY SYSTEM REGISTRAR

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Name of Company	Certified Quality Management System	Certificate Reference(s)
Intertek Services	ISO 13485:2016	0084059

Biodex Medical Systems declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745
- Directive 2011/65/EU (RoHS 2)
- Directive 2015/863/EU (RoHS 3)
- Directive 2017/2102/EU
- Directive 2006/42/EC (Machinery Directive)

COMPANY REPRESENTATIVE: Amaris Ajamil, PhD, RAC

TITLE: Vice President, Quality and Regulatory Affairs, Salona Global

SIGNATURE: Amaris Ajamil
Amaris Ajamil (Oct 9, 2023 10:27 EDT)

PLACE: Shirley, New York, USA

No. 111a Rev. Q

S4 PRO 111A REV. Q

Final Audit Report 2023-10-09

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