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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 Quick Set	840-000
Contains MODEL NUMBER(s) <u>840-000 System 4 Quick Set includes:</u> 850-000-E300 Dell CPU 840-109-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) 840-000-K900 Quick Set 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 830-271 Anti-Shear, Right 830-240 Attachment Rack 835-135-A000 Quick Set Single Chair Assembly 840-140-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

Biodex Medical Systems, Inc.

49 Natcon Drive, Shirley, New York, 11967-4704, Tel:800-224-6339 (Int'l 631-924-9000), Fax:631-924-9241, Email: info@biodexrehab.com, www.biodex.com

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RISK CLASS FOR DEVICES		
Device Classification		Common Specifications / Standards
Class:	Ila	<ul style="list-style-type: none"> • 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		
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:

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- 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 10:26 EDT)

PLACE: Shirley, New York, USA

No. 111B Rev. Q

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Final Audit Report

2023-10-09

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