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DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Isokinetic Testing and Evaluation System	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

Serial Number [ENTER]

MANUFACTURER

Name of Company	Address	Representative
Biodex Medical Systems, Inc.	20 Ramsey Road Shirley, NY 11967-4704 USA	Paul Cadmus Acting Vice President, Regulatory Affairs & Compliance

AUTHORIZED REPRESENTATIVE

Name of Company	Address	Telephone/Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	Phone: +31.70.345.8570 Fax: +31.70.346.8570

REGISTRATION INFORMATION

Notified Body and ID#	CE Certificate No & Expiration Date	Date CE Marking First Applied
Intertek Services	41313009-01 July 20, 2023	N/A

Biodex Medical Systems, Inc.

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

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CONFORMITY ASSESSMENT

Device Classification	Route to Compliance	Standards Application
Class IIa Rule 9	Annex II of MDD 93/42/EEC Council Directive	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) ANSI/AAMI ES60601-1:2005 + A1:2012 + C1:2009 and A2:2010 CAN/CSA-C22.2 No. 60601-1:2014 IEC 60601-1-2:2014

QUALITY SYSTEM REGISTRAR

Intertek Services
Certified Quality Management System:
ISO 13485:2016 Certificate: 0084059

Biodex Medical Systems, Inc. declares the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices.

Company Representative: Paul Cadmus

Title: Acting Vice President, Regulatory Affairs & Compliance

Date: April 14, 2020

No. 111a Rev. M

Signature:



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