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DECLARATION OF CONFORMITY

PRODUCT INDENTIFICATION		
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

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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 of 14 June 1993 for Medical Devices amended up to and inclusive of Council Directive 2007/47/EC (MDD) (LVFS 2003:11 as amended by LVFS 2009:07).

Company Representative: Paul Cadmus
Title: Acting Vice President, Regulatory Affairs & Compliance
Date: November 25, 2020

No. 111a Rev. N
Signature:

Biodex Medical Systems, Inc.
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