

# BIODEX

## DECLARATION OF CONFORMITY

### PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Isokinetic Testing and Evaluation System	System 4 Quick Set	840-000

#### Contains

MODEL NUMBER(s)

#### **840-000 System 4 Quick Set includes:**

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

Serial Number [ENTER]

### MANUFACTURER

Name of Company	Address	Representative
Biodex Medical Systems, Inc.	20 Ramsey Road Shirley, NY 11967-4704 USA	Clyde Schlein <i>Vice President, Regulatory Affairs &amp; Compliance</i>

### 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	Annex II of MDD	EN 6060101, 3 <sup>rd</sup> Ed
Rule 9	93/42/EEC Council Directive	EN 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:** Clyde Schlein

**Title:** Vice President, Regulatory Affairs & Compliance

**Date:** May 1, 2019

No. 111b Rev. L

Signature:



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