### PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>Type of Equipment</th>
<th>Product Name(s)</th>
<th>Model/Number(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isokinetic Testing and Evaluation System</td>
<td>System 4 Pro</td>
<td>850-000</td>
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</tbody>
</table>

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
  - 820-155 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
  - 830-271 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

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### MANUFACTURER

**Name of Company**: Biodex Medical Systems, Inc.

**Address**: 20 Ramsey Road
Shirley, NY 11967-4704
USA

**Representative**: Clyde Schlein
Vice President, Regulatory Affairs & Compliance

### AUTHORIZED REPRESENTATIVE

**Name of Company**: Emergo Europe

**Address**: Prinsessegang 20
2514 AP The Hague
The Netherlands

**Telephone/Email**: Phone: +31.70.345.8570
Fax: +31.70.346.8570

### REGISTRATION INFORMATION

**Notified Body and ID#**: Intertek Services

**CE Certificate No & Expiration Date**: 41313009-01 July 20, 2023

**Date CE Marking First Applied**: N/A
**CONFORMITY ASSESSMENT**

<table>
<thead>
<tr>
<th>Device Classification</th>
<th>Route to Compliance</th>
<th>Standards Application</th>
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<tbody>
<tr>
<td>Class IIa</td>
<td>Annex II of MDD</td>
<td>EN 6060101, 3rd Ed</td>
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**QUALITY SYSTEM REGISTRAR**

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<tr>
<th>Intertek Services</th>
<th>Certified Quality Management System:</th>
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<tbody>
<tr>
<td></td>
<td>ISO 13485:2016 Certificate: 0084059</td>
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</table>


**Company Representative:** Clyde Schlein  
**Title:** Vice President, Regulatory Affairs & Compliance  
**Date:** May 1, 2019

No. 111a  Rev. L

Signature: