## DECLARATION OF CONFORMITY

<table>
<thead>
<tr>
<th>APPLICATION OF COUNCIL DIRECTIVE(s)</th>
<th>93/42/EEC as amended by 2007/47/EC : LVFS 2003:11</th>
</tr>
</thead>
<tbody>
<tr>
<td>AND NATIONAL REGULATION OF SWEDEN</td>
<td></td>
</tr>
<tr>
<td>DATE OF ISSUE</td>
<td>November 29, 2017</td>
</tr>
<tr>
<td>TYPE OF EQUIPMENT</td>
<td>Upgrade Bundle converts Biodex System 3 to Biodex System 4</td>
</tr>
<tr>
<td>BRANDNAME</td>
<td>Biodex</td>
</tr>
<tr>
<td>MODEL NUMBER(s)</td>
<td>850-830 Components of 840-000, 850-000</td>
</tr>
<tr>
<td>SERIAL NUMBER</td>
<td>SAMPLE</td>
</tr>
</tbody>
</table>

### STANDARD(s) TO WHICH UNIT CONFORMITY IS DECLARED

- IEC 60601-1-2: 2001 2\textsuperscript{ND} Edition, Rev. 2
- EN 60601-1-1: 2000
- IEC 60601-1-4: 2000 Ed 1.1

### ISO 9001:2008 CERTIFICATE

- \#98-1091h-03

### ISO 13485:2003 CERTIFICATE

- \#9060

### CLASS

- II a Annex II

### QUALITY SYSTEM REGISTRAR

- INTERTEK SERVICES

### ISSUED BY MANUFACTURER:

- Biodex Medical Systems, Inc.
- 20 Ramsey Road
- Shirley, New York 11967-4704 USA

I, the undersigned, hereby declare that the equipment specified above conforms to the Directive(s) and Standard(s) as specified.

\[signature\]

Clyde Schlein
Vice President, Regulatory Affairs & Compliance

CD-CC-111.1-comp rev D