


# BIODEX

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

## DECLARATION OF CONFORMITY

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| <b>APPLICATION OF COUNCIL DIRECTIVE(S)<br/>AND NATIONAL REGULATION OF SWEDEN</b>   | 93/42/EEC as amended by<br>2007/47/EC : LVFS 2003:11   |
| <b>DATE OF ISSUE</b>   | <b>September 25, 2018</b>  |
| <b>TYPE OF EQUIPMENT</b>   | Force Measuring Platform   |
| <b>BRANDNAME</b>   | Balance System SD  |
| <b>MODEL NUMBER(s)</b>   | 950-440, 950-441, 950-444  |
| <b>SERIAL NUMBER</b>   | <b>SAMPLE</b>  |
| <b>STANDARD(s) TO WHICH UNIT<br/>CONFORMITY IS DECLARED</b>  | IEC/EN 60601-1 Ed 3<br>IEC 60601-1-2:2007 Ed 3<br>UL 60601-1:2003 Ed 1 Rev 2006<br>CAN/CSA C22.2 601-1-M90 |
| <b>CLASS</b>   | I Measuring Annex V  |
| <b>QUALITY SYSTEM REGISTRAR</b>  | INTERTEK SERVICES  |
| <b>CE IDENTIFICATION #</b>   | 0413<br>                 |
| <b>E.C. CERTIFICATE # &amp; Expiration Date</b>  | 41312068-01 July 20, 2023  |
| <b>BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM</b><br>ISO 13485:2003 CERTIFICATE #9060-5-03   |  |
| <b>ISSUED BY MANUFACTURER:</b><br>Biodex Medical Systems, Inc.<br>20 Ramsey Road<br>Shirley, New York 11967-4704 USA<br>I, the undersigned, hereby declare that the equipment specified above conforms to the Directive(s) and Standard(s) as specified. |  |

### Authorized European Representative



signature

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



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#CD-CC-107 rev L