

# BIODEX

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

## DECLARATION OF CONFORMITY

<b>DATE OF ISSUE</b>	<b>September 25, 2018</b>
<b>TYPE OF EQUIPMENT</b>	Ergometer
<b>BRANDNAME</b>	<b>BIOSTEP 2</b>
<b>MODEL NUMBER(s)</b>	950-240
<b>SERIAL NUMBER</b>	<b>SAMPLE</b>
<b>BRANDNAME</b>	<b>UPPER BODY CYCLE (UBC)</b>
<b>MODEL NUMBER(s)</b>	950-146, 950-148
<b>SERIAL NUMBER</b>	<b>SAMPLE</b>
<b>BRANDNAME</b>	<b>PRESTEP</b>
<b>MODEL NUMBER(s)</b>	950-246
<b>SERIAL NUMBER</b>	<b>SAMPLE</b>
<b>STANDARD(s) TO WHICH UNIT CONFORMITY IS DECLARED</b>	EN 60601-1-2:2007 IEC 601-1:1998+A1:1991+A2:1995 UL 60601-1, 1 <sup>st</sup> Ed., 04/25/2003 CAN/CSA C22.2 No.:601-1-M90 (R2005)
<b>CLASS</b>	I Measuring Annex V
<b>QUALITY SYSTEM REGISTRAR</b>	INTERTEK SERVICES
<b>BIODEX CERTIFIED QUALITY MANAGEMENT SYSTEM</b> ISO 13485:2003 CERTIFICATE #9060-5-03	

The BioStep 2 / UBC / PRESTEP are manufactured in compliance to the product's specifications and meets the above referenced Standards.

### 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-141 rev D