

BIODEX

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

DECLARATION OF CONFORMITY

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

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