

BIODEX

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Ergometer	BioStep™2	950-240
	Upper Body Cycle (UBC)	950-146, 150-148
	PreStep	950-246

Serial Number [ENTER]

MANUFACTURER

Name of Company	Address	Representative
Biodex Medical Systems, Inc.	20 Ramsey Road Shirley, NY 11967-4704 USA	Clyde Schlein <i>Vice President, Regulatory Affairs & Compliance</i>

CONFORMITY ASSESSMENT

Device Classification	Route to Compliance	Standards Application
NON CE	N/A	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)

QUALITY SYSTEM REGISTRAR

Intertek Services Certified Quality Management System:
ISO 13485:2016 Certificate: 0084059

The BioStep™2 / UBC / PreStep are manufactured in compliance to the product's specifications and meets the above referenced Standards. The products are non-medical.

Company Representative: Clyde Schlein

Title: Vice President, Regulatory Affairs & Compliance

Date: May 1, 2019

No. 141 Rev. E

Signature:



Biodex Medical Systems, Inc.

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