

# BIODEX

## DECLARATION OF CONFORMITY

### PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Force Measuring Platform	BioSway	950-460, 950-461

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 &amp; Compliance</i>

### CONFORMITY ASSESSMENT

Device Classification	Route to Compliance	Standards Application
Non CE	Annex V of MDD 93/42/EEC	EN 60601-1-2:2007
Class I Measuring Rule 9	Council Directive  EC Certificate: 41312068-01 Expiration Date: July 20, 2023	IEC 601-1:1988+A1:1991+A2:1995 UL 6060101, 1 <sup>st</sup> Ed., 4/25/2003 CAN/CSA C22.2 No.:601-1-M90 (R2005)

### QUALITY SYSTEM REGISTRAR

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

**Company Representative:** Clyde Schlein  
**Title:** Vice President, Regulatory Affairs & Compliance  
**Date:** May 1, 2019

No. 129 Rev. G

Signature:

