

# BIODEX

## DECLARATION OF CONFORMITY

### PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Force Measuring Platform	Balance System SD	950-430, 950-440, 950-441, 950-444, 950-450

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>

### AUTHORIZED REPRESENTATIVE

Name of Company	Address	Telephone/Email
Ergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	Phone: +31.70.345.8570 Fax: +31.70.346.8570

### REGISTRATION INFORMATION

Notified Body and ID#	CE Certificate No & Expiration Date	Date CE Marking First Applied
Intertek Services	41312068-01 July 20, 2023	N/A

### CONFORMITY ASSESSMENT

Device Classification	Route to Compliance	Standards Application
Class I Measuring Rule 9	Annex V of MDD 93/42/EEC Council Directive	IEC/EN 60601-1, Ed 3 IEC 60601-1-2:2007, Ed 3 UL 60601-1:2003, Ed 1 rev 2006 CAN/CSA C22.2 No.:601-1-M90

### QUALITY SYSTEM REGISTRAR

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

Biodex Medical Systems, Inc. declares the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices.

**Company Representative:** Clyde Schlein

**Title:** Vice President, Regulatory Affairs & Compliance

**Date:** May 1, 2019

No. 107 Rev. M

Biodex Medical Systems, Inc.

20 Ramsey Road, Shirley, New York, 11967-4704, Tel: 800-224-6339 (Int'l 631-924-9000), Fax: 631-924-9241, Email: info@biodex.com, www.biodex.com

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Signature:

A handwritten signature in black ink, appearing to read "G. Galati", written over a horizontal line.

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