BIODEX

DECLARATION OF CONFORMITY

PRODUCT INDENTIFICATION		
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	Paul Cadmus *Acting Vice President, Regulatory Affairs & Compliance*

AUTHORIZED REPRESENTATIVE		
Name of Company	**Address**	**Telephone/Email**
Emergo 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 12	Annex V of MDD 93/42/EEC Council Directive	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) ANSI/AAMI ES60601-1:2005 + A1:2012 + C1:2009 and A2:2010 CAN/CSA-C22.2 No. 60601-1:2014 IEC 60601-1-2:2014 / EN 60601-1-2:2014 EN 301 489-17 V3.2.0:2017 IEEE/ANSI C63.27-2017 KDB447498 Appendix A

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: Paul Cadmus
Title: Acting Vice President, Regulatory Affairs & Compliance
Date: April 29, 2020

No. 107 Rev. O
Signature:

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