

BIODEX

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Powered Exercise Equipment	Gait Trainer 3 Treadmill	950-400, 950-401, 950-402 950-403, 950-404, 950-405 950-406, 950-407, 950-408 950-413

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 60601-1-2:2015

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 1, 2020

No. 137 Rev. J

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