BIODEX

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Biodex Medical Systems, Inc	49 Natcon Dr Shirley, NY 11967, USA	US-MF-000028834

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Phone/email**
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION	
Product Name	**Code / Catalog Number**
Gait Trainer 3 Treadmill	950-401, 950-403, 950-407
Intended Purpose	**Basic UDI-DI**
The Biodex Gait Trainer 3 is an assessment tool for measurement of functional gait. It is a versatile product, providing capabilities for objective measurements of specific gait parameters as well as physiological measures of kinesthetic, proprioceptive abilities and neuromuscular control. It is intended to be used as a training tool to assist patients with Gait Velocity, Average Step Cycle Time, Average Step Length, Co-efficient of Variation, and Time on Each Foot.	71817521759

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	Im	• ISO 13485:2016 • ISO 14971: 2019 • 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
Rule:	13	

NOTIFIED BODY			
Name of Company	**ID Number**	**Conformity Assessment Procedure**	**Certificate Reference(s)**
Intertek Medical Notified Body AB	2862	EU Regulation 2017/745 MDR Annex IX Chapters I & III	28620184965

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QUALITY SYSTEM REGISTRAR		
Name of Company	**Certified Quality Management System**	**Certificate Reference(s)**
Intertek Services	ISO 13485:2016	0084059

Biodex Medical Systems declares that the above-mentioned products meet the provision of the following EU legislation:

- EU Regulation 2017/745 (Medical Device Regulation)
- Directive 2011/65/EU (RoHS 2)
- Directive 2015/863/EU (RoHS 3)
- Directive 2017/2102/EU
- Directive 2006/42/EC (Machinery Directive)

COMPANY REPRESENTATIVE: Amaris Ajamil, PhD, RAC

TITLE: Vice President, Quality and Regulatory Affairs, Salona Global

SIGNATURE: Amaris Ajamil

PLACE: Shirley, New York, USA **DATE:** 12/09/2024

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