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**
Vibrotactile System	950-430
Intended Purpose	**Basic UDI-DI**
Accessory to Balance SD (Force Measuring Platform)	07181752095A

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	I	• 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 • EN 301 489-17 V3.2.0:2017 • IEEE/ANSI C63.27-2017
Rule:	13	

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

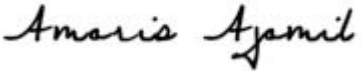
Biodex Medical Systems declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Device Regulation 2017/745
- 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: 

PLACE: Shirley, New York, USA **DATE:** 13/09/2023

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