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**
Balance System SD	950-441
Intended Purpose	**Basic UDI-DI**
The Balance System SD is an assessment tool which allows for testing and training in both static and dynamic formats. It is a versatile product, providing capabilities for balance assessment, concussion management, measurement of kinesthetic and proprioceptive abilities, and determining neuromuscular control (stability and degree of sway values).	07181752095A

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	Im	• ISO 13485:2016 • ISO 14971: 2019 • ANSI/AAMI ES60601-1:2005/A2:2021 • CAN/CSA C22.2 No. 60601-1:2014 + A2:2022 • IEC 60601-1-2:2014 • EN 60601-1-2:2015 • EN 301 489-17 V3.2.0:2017 • IEEE/ANSI C63.27-2017 • KDB447498 Appendix A
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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