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**
Dual Position Ex/Flex Back Attachment	830-450
Closed Chain Attachment	830-520
UE Hemiparetic Attachments	830-540
Pediatric Left Knee Attachment	830-474
Pediatric Right Knee Attachment	830-475
Pediatric Shoulder Attachment	821-321
Pediatric Hip Attachment	830-316
Hamstring (set) Attachment	830-550
Work Simulation Tools Attachment	830-269
Left Pivot Anti-Shear Attachment	830-260
Right Pivot Anti-Shear Attachment	830-261
Chair Wedge	830-113
Intended Purpose	**Basic UDI-DI**
System 4 Attachments are medical device accessories intended to assist a medical device in the identification and treatment of physical impairments that cause functional limitations typical of sports injuries, orthopedics, pediatric medicine, and neurorehabilitation.	07181752014S

RISK CLASS FOR DEVICES		
Device Classification		**Common Specifications / Standards**
Class:	I	• **ISO 13485:2016** Medical devices -- Quality management systems -- Requirements for regulatory purposes • **ISO 14971: 2019** Medical devices -- Application of risk management to medical devices • **ISO 15223-1:2021** Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
Rule:	1	

		• **ISO 7000:2019** Graphical symbols for use on equipment -- Registered symbols • **ISO 10993-1:2018** Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

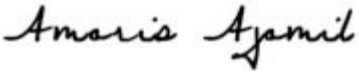
QUALITY SYSTEM REGISTRAR		
Name of Company	**Certified Quality Management System**	**Certificate Reference(s)**
Intertek Services	ISO 13485:2016	0084059

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

- Medical Devices Regulation (EU) 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:** 04/04/2024