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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
Unweighing System, NxStep	945-480, 950-485
Intended Purpose	Basic UDI-DI
Partial Body Weight Support Training	071817521657

RISK CLASS FOR DEVICES	
Device Classification	Common Specifications / Standards
Class: I	<ul style="list-style-type: none">• 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
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:

- EU 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

Biodex Medical Systems, Inc.

49 Natcon Drive, Shirley, New York, 11967-4704, Tel:800-224-6339 (Int'l 631-924-9000), Fax:631-924-9241, Email: info@biodexrehab.com, www.biodex.com

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

SIGNATURE: *Amaris Ajamil*
Amaris Ajamil (Feb 19, 2024 09:34 EST)

19/02/2024

PLACE: Shirley, New York, USA

No. 145 Rev. F



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NxStep Unweighing Declaration of Conformity Rev F

Final Audit Report

2024-02-19

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