

BIODEX

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Type of Equipment	Product Name(s)	Model/Number(s)
Partial Body Weight Support Training	Unweighing System, NxStep	945-480, 950-485

Serial Number N/A

MANUFACTURER

Name of Company	Address	Representative
Biodex Medical Systems, Inc.	20 Ramsey Road Shirley, NY 11967-4704 USA	Paul Cadmus Acting Vice President, Regulatory Affairs & Compliance

AUTHORIZED REPRESENTATIVE

Name of Company	Address	Telephone/Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	Phone: +31.70.345.8570 Fax: +31.70.346.8570

CONFORMITY ASSESSMENT

Device Classification	Route to Compliance	Standards Application
Class I Rule 12	Annex VII of MDD 93/42/EEC Council Directive	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

QUALITY SYSTEM REGISTRAR

Intertek Services Certified Quality Management System:
ISO 13485:2016 Certificate: 0084059

Biodex Medical Systems, Inc. declares the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices.

Company Representative: Paul Cadmus

Title: Acting Vice President, Regulatory Affairs & Compliance

Date: April 1, 2020

No. 145 Rev. C

Signature:



Biodex Medical Systems, Inc.

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