

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	Clyde Schlein <i>Vice President, Regulatory Affairs & Compliance</i>

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 IEC 60601-1 clause 15.3.5 IEC 60601-1 3 rd Ed, clause 9.4 IEC 60601-1 3 rd Ed, clause 7.9 ISO 10535 clause 6 EN 60601-1-2

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.

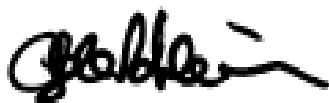
Company Representative: Clyde Schlein

Title: Vice President, Regulatory Affairs & Compliance

Date: May 1, 2019

No. 145 Rev. B

Signature:



Biodex Medical Systems, Inc.

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