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EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Biodex Medical Systems, Inc

20 Ramsay Road, Shirley, NY 11967, USA

Product Category:

Physical therapy and rehabilitation equipment, class 1 with measuring function.

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:
41312068-01

Initial Certification Date:
20 July 1998

Certificate Valid from:
21 July 2018

Certificate Expiry Date:
20 July 2023

SWEDAC ACKREDITERING
Ackred. nr 1003
ISO/IEC 17021

Pontus Gedda
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

19 July 2018
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

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MDD – Product List

Products included in the Certificate No: 41312068-01
Issued to: Biodex Medical Systems, Inc.
20 Ramsey Road
11967 Shirley, New York
USA

Product category	Type/Model designation	Class	Measuring	GMDN code (not mandatory)	Date added
Physical Therapy and Rehabilitation Equipment					
Treadmills	Gait trainer 3 950-400, 950-401, 950-402, 950-403, 950-404, 950-405, 950-406, 950-407, 950-408	I	Yes		May 24, 2011
Balance System		I	Yes		
	Balance SD 950-440, 950-441, 950-444				Nov 19, 2010
					*
	BioSway 950-460, 950-461				Nov 19, 2010
Offset Unweighing System		I	Yes		
	945-480				*

* Product added before February 4, 2010.

Signed Date: 19 July 2018
Valid Date: 21 July 2018

Intertek Semko AB
Notified Body MDD

Pontus Gedda
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00, Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com
Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Decision Report

Certificate No: 41312068-01
Date: 19 July 2018
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Biodex Medical Systems, Inc
Attn: Clyde Schlein
20 Ramsey Road
11967-0702 Shirley, New York
USA

Purpose	Assessment to issue a new certificate due to five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V.
Activity	Certification audit was performed 26 June 2017 in Shirley, New York by Richard Auringer and Luis Lopes.
Scope of assessment	Physical therapy and rehabilitation equipment, Class I(m)
Result	2 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	21 July 2018
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Pontus Gedda
Certification Authority MDD