

EC Certificate

PRODUCTION QUALITY ASSURANCE

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

Certificate Number
41312068

Initial Certification Date
July 20, 1998

Certificate Issue Date
July 21, 2013

Certificate Expiry Date
July 20, 2018

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.

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

We hereby declare that an examination of the under mentioned production quality assurance system - restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements - 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, PO Box 702, Shirley, NY 11967-0702, 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.

July 9, 2013

Signed date


Hans Ericsson, Certification Authority MDD
Intertek Semko AB, Kista, Sweden

Products included in the Certificate No: 41312068
 Issued to: Biodex Medical Systems, Inc.
 20 Ramsey Road
 11967-0702 Shirley, New York
 USA

Product category	Type/Model designation	Class	Measuring	GMDN code <small>(not mandatory)</small>	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	Balance SD 950-440, 950-441, 950-444	I	Yes		Nov 19, 2010
	BioSway 950-460, 950-461				*
Offset Unweighing System	945-480	I	Yes		*

* Product added before February 4, 2010.

Date of Issue: November 16, 2017

Intertek Semko AB
 Notified Body MDD



Peter Nermander
 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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Product List for Certificate No: 41312068
 Date: November 16, 2017
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