

# 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 - 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.

Main Site: 20 Ramsey Road, Shirley, New York, 11967, United States

**Product Category:**

- Physical therapy and rehabilitation equipment, Class I with measuring function.

**Certificate Number:**

41312068-02

**Initial Certification Date:**

20 July 1998

**Certificate Valid from:**

22 March 2021

**Certificate Expiry Date:**

20 July 2023



**Mikael Hagelin**  
Certification Authority MDD  
Intertek Semko AB, Kista, Sweden

22 March 2021

**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.



Products included in the Certificate No: 41312068-02  
 Issued to: Biodex Medical Systems, Inc.  
 20 Ramsey Road  
 11967 Shirley, New York  
 USA

Product category	Type/Model designation	Class	Measuring	GMDN code <small>(not mandatory)</small>	Date added
<b>Physical Therapy and Rehabilitation Equipment</b>					
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		Nov 19, 2010
					*

\* Product added before February 4, 2010.

Signed Date: 22 March 2021  
 Valid Date: 22 March 2021

**Intertek Semko AB**  
 Notified Body MDD



Mikael Hagelin  
 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.

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

Product List for Certificate No: 41312068-02  
 Date: 22 March 2021  
 Page 1 of 1