

# EC Certificate

## FULL QUALITY ASSURANCE SYSTEM

### Directive 93/42/EEC on Medical Devices, Annex II (3)

**Certificate Number**  
41313009

**Initial Certification Date**  
July 20, 2003

**Certificate Issue Date**  
July 21, 2013

**Certificate Expiry Date**  
July 20, 2018

We hereby declare that an examination of the under mentioned full 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 II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

*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*

#### Organization:

## **Biodex Medical Systems, Inc**

20 Ramsay Road, Shirley, NY 11967-0702, USA

#### Product Category:

- Physical therapy and rehabilitation equipment
- Medical spectrometers

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

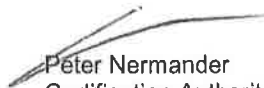
Products included in the Certificate No: 41313009  
 Issued to: **Biodex Medical Systems, Inc.**  
 20 Ramsey Road  
 11967-0702 Shirley, New York  
 USA

Product category	Type/Model designation	Class	Measuring	GMDN code <small>(not mandatory)</small>	Date added
Physical Therapy and Rehabilitation Equipment	System 4	Ila	No	-	*
Medical Spectrometers	Atomlab 960 187-600, 187-601	Ila	No	-	Jan 25, 2013

\* Product added before January 25, 2013.

Date of Issue: October 24, 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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