

# EC Certificate

**PRODUCTION QUALITY ASSURANCE**  
**Directive 93/42/EEC on Medical Devices, Annex V**

**Certificate Number**  
41312458

**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, Shirley, NY 11967-0702, USA

**Product Category:**

Radionuclide calibrators,  
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

# MDD – Product List

Products included in the certificate no: 41312458  
Issued to: Biodex Medical Systems, Inc.  
20 Ramsey Road  
Shirley, NY 1967-0702  
USA

| Product category         | Type/Model designation                               | Class | Measuring Function | GMDN code<br>(not mandatory) |
|--------------------------|--|-------|--------------------|------------------------------|
| Radionuclide Calibrators | Atomlab 400<br>086-335                               | I     | Yes                |                              |
|                          | Atomlab 500<br>086-330, 086-331, 086-332,<br>086-336 | I     | Yes                |                              |

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.

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: 41312458  
Date: October 24, 2017

Page 1 of 1