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EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

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.

Organization:

Biodex Medical Systems, Inc.

Main Site: 20 Ramsay Road, Shirley, NY 11967, USA

Product Category:

- Physical therapy and rehabilitation equipment

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

Certificate Number:
41313009-02

Initial Certification Date:
20 July 2003

Certificate Valid from:
10 February 2020

Certificate Expiry Date:
20 July 2023

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

10 February 2020
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.

MDD – Product List

Products included in the Certificate No: 41313009-02
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	System 4	IIa	No	-	*

* Product added before January 25, 2013.

Signed date: 10 February 2020
Date of Issue: 10 February 2020

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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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.intertek.se
Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Product Decision

Certificate No: 41313009-02
Date: 10 February 2020
Handled by: Beverley Oakley
E-mail: medtechsweden@intertek.com

Biodex Medical Systems, Inc.
Attn: Julia Dzakonski
20 Ramsey Road,
Shirley, NY 11967,
USA

Purpose

Assessment of the notification dated January 28, 2020 for removal of products from your quality system certified according to LVFS 2003:11, Annex II (Swedish implementation of MDD 93/42/EEC).

Products concerned

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)
Medical Spectrometers	AtomLab 960 187-600, 187-601	IIa	No	-

Conclusions/Decisions

The products are no longer sold within Europe due to commercial reasons.

Due to the removal, the previously issued warning letter has now been retracted.

The notification has been accepted and the products can be removed.

As the device is the only item in the product category "*Medical Spectrometers*", this product category will also be removed from your certificate and an updated certificate will be issued separately.

Follow-up assessments

At the next audit your auditor may follow-up on the changes to products in the Quality system.

Appeals

Any appeal against this decision will be processed by an appeals panel at Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD