

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 Ramsey Road, Shirley, New York, 11967, United States

Product Category:

- Physical therapy and rehabilitation equipment

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

Certificate Number:

41313009-03

Initial Certification Date:

20 July 2003

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.



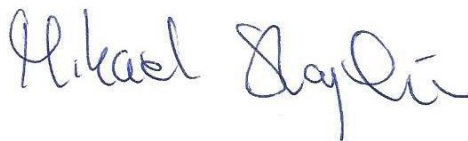
Products included in the Certificate No: 41313009-03
Issued to: **Biodex Medical Systems, Inc.**
20 Ramsey Road
11967 Shirley, New York
USA

Product category	Type/Model designation	Class	Measuring	GMDN code <small>(not mandatory)</small>	Date added
Physical Therapy and Rehabilitation Equipment	System 4	Ila	No	-	*

* Product added before January 25, 2013.

Signed date: 22 March 2021
Date of Issue: 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.
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