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

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

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.

MDD – Product List

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 (not mandatory)	Date added
Physical Therapy and Rehabilitation Equipment	System 4	IIa	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.

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

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

Biodex Medical Systems, Inc
49 Natcon Drive
Shirley, New York 11967
United States

2023-08-24

Notified Body Confirmation Letter
Reference: 41312068, 41313009 - CN00273-02

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Intertek Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2862 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Biodex Medical Systems, Inc
49 Natcon Drive
Shirley, New York 11967
United States
SRN Number: Not yet provided (application pending)

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a

Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Brian Mather
Certification Manager
Intertek Medical Notified Body AB

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Ref Number/ Device Identification	Device Name	Device classification	MDD Certificate Reference(s)
945-480	NxStep Unweighing System	Im	41312068
950-000	Gait Trainer 3, 115 VAC, Support Bar	Im	41312068
950-401	Gait Trainer 3, 230 VAC, Support Bar	Im	41312068
950-401-BR	Gait Trainer 3, 230 VAC, Support Bar (Brazil)	Im	41312068
950-402	Gait Trainer 3, 115 VAC, Extended Hand Rails	Im	41312068
950-403	Gait Trainer 3, 115 VAC, Extended Hand Rails	Im	41312068
950-403-BR	Gait Trainer 3, 115 VAC, Extended Hand Rails (Brazil)	Im	41312068
950-404	Gait Trainer 3, 100 VAC, Support Bar (Japan)	Im	41312068
950-405	Gait Trainer 3, 100 VAC, Extended Hand Rails (Japan)	Im	41312068
950-406	Gait Trainer 3, 115 VAC, Geriatric/Pediatric Handrails	Im	41312068
950-407	Gait Trainer 3, 230 VAC, Geriatric/Pediatric Handrails	Im	41312068
950-407-BR	Gait Trainer 3, 230 VAC, Geriatric/Pediatric Handrails	Im	41312068
950-408	Gait Trainer 3, 100 VAC, Geriatric/Pediatric Handrails (Japan)	Im	41312068
950-440	Balance System SD, 115V AC	Im	41312068
950-441	Balance System SD, 230 V AC	Im	41312068
950-441-BR	Balance System SD, 230 V AC (Brazil)	Im	41312068
950-444	Balance System SD, 100V AC	Im	41312068
950-460	Biosway, 115V/230V	Im	41312068
840-000	System 4 Quick Set	IIa	41313009
850-000	System 4 Pro	IIa	41313009
852-000	System 4 MVP	IIa	41313009

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Ref Number/ Device Identification	Device Name	Device classification	MDD Certificate Reference(s)
N/A			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action