# EC CERTIFICATION

## QUALITY MANAGEMENT SYSTEM CERTIFICATE

### EU Regulation 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation restricted to the aspects relating to the conformity of the devices with metrological requirements - has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

**Certificate Number:**
28620184965

**Revision:**
00

**Initial Certification Date:**
22 August 2024

**Date of Certification Decision:**
22 August 2024

**Certificate Issue Date:**
22 August 2024

**Certificate Expiry Date:**
2 December 2028

## Biodex Medical Systems, Inc

49 Natcon Drive Shirley, New York 11967 United States

Manufacturer SRN: US-MF-000028834

Authorised Representative Name

**Emergo Europe**

Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

**Scope:**

Metrology aspects of devices as detailed in attached product list.

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

## PRODUCT LIST FOR CERTIFICATE

*See attached Product List*

## EXAMINATION AND TESTS PERFORMED

| | |
|---|---|
| **Last Audit report reference** | **Stage 1 audit ACTY-2022-582741** |
| | **Stage 2 audit ACTY-2022-582742** |
| | |

## CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

| |
|---|
| None |

## CERTIFICATE HISTORY

| PRECEDING CERTIFICATE NUMBER | DATE OF ISSUE | IDENTIFICATION OF CHANGES |
|---|---|---|
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| | | |

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# PRODUCT LIST FOR CERTIFICATE

**Issued to:** Biodex Medical Systems, Inc

**Certificate number:** 28620184965

**Certificate valid from:** 2024-08-22

**Product List Issue Date:**
22 August 2024

| Product | Classification and EMDN | Intended use[1] | Date Added |
|---|---|---|---|
| **Class I devices with a measuring function** | | | |
| ***Basic UDI-DI: 07181752095A*** | | | |
| 950-440 - Balance System SD, 115V AC | Class I(m) Z12062402 | | 2024-08-22 |
| 950-441 - Balance System SD, 230 V AC | Class I(m) Z12062402 | | 2024-08-22 |
| 950-441-BR - Balance System SD, 230 V AC (Brazil) | Class I(m) Z12062402 | | 2024-08-22 |
| 950-444 - Balance System SD, 100V AC | Class I(m) Z12062402 | | 2024-08-22 |
| 950-460 - Biosway, 115V/230V | Class I(m) Z12062402 | | 2024-08-22 |
| ***Basic UDI-DI: 71817521657*** | | | |
| 945-480 - NxStep Unweighing System | Class I(m) Z12069002 | | 2024-08-22 |
| ***Basic UDI-DI: 71817521759*** | | | |
| 950-000 - Gait Trainer 3, 115 VAC, Support Bar | Class I(m) Z129006 | | 2024-08-22 |
| 950-401-BR - Gait Trainer 3, 230 VAC, Support Bar (Brazil) | Class I(m) Z129006 | | 2024-08-22 |
| 950-401 - Gait Trainer 3, 230 VAC, Support Bar | Class I(m) Z129006 | | 2024-08-22 |
| 950-402 - Gait Trainer 3, 115 VAC, Extended Hand Rails | Class I(m) Z129006 | | 2024-08-22 |
| 950-403-BR - Gait Trainer 3, 115 VAC, Extended Hand Rails (Brazil) | Class I(m) Z129006 | | 2024-08-22 |
| 950-403 - Gait Trainer 3, 115 VAC, Extended Hand Rails | Class I(m) Z129006 | | 2024-08-22 |
| 950-404 - Gait Trainer 3, 100 VAC, Support Bar (Japan) | Class I(m) Z129006 | | 2024-08-22 |
| 950-405 - Gait Trainer 3, 100 VAC, Extended Hand Rails (Japan) | Class I(m) Z129006 | | 2024-08-22 |
| 950-406 - Gait Trainer 3, 115 VAC, Geriatric/Pediatric Handrails | Class I(m) Z129006 | | 2024-08-22 |

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

| Product | Classification and EMDN | Intended use[1] | Date Added |
|---|---|---|---|
| 950-407-BR - Gait Trainer 3, 230 VAC, Geriatric/Pediatric Handrails | Class I(m) Z129006 | | 2024-08-22 |
| 950-407 - Gait Trainer 3, 230 VAC, Geriatric/Pediatric Handrails | Class I(m) Z129006 | | 2024-08-22 |
| 950-408 - Gait Trainer 3, 100 VAC, Geriatric/Pediatric Handrails (Japan) | Class I(m) Z129006 | | 2024-08-22 |

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*Certificate number:* 28620184965
*Product list issue date:* 22 August 2024