



Certificate No. 8770-5-2023

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Two Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer/Distributor

BIODEX MEDICAL SYSTEMS, INC.
 49 Natcon Drive
 Shirley, NY USA 11967

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
 DRP2: Division of Establishment Support
 Office of Regulatory Programs
 Office of Product Evaluation and Quality
 Center for Devices and Radiological Health
 U.S. Food and Drug Administration, DHHS

This certificate is valid from May 08, 2023 to May 07, 2025.



E04514161



Certificate No. 8770-5-2023

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Manufacturer/Distributor

BIODEX MEDICAL SYSTEMS, INC.
49 Natcon Drive
Shirley, NY
USA 11967

Name of Product(s)

NONMEASURING EXERCISER,
Sit2Stand Squat Assist,
ISOKINETIC SYSTEMS
S4 Pro
S4 MVP
S4 Quick Set
System 4 Options
Dual Position Back Extension/Flexion
Attachment Clamp
Closed Kinetic Chain Attachment
Work Simulation Tools
Hamstring Attachment
Seat Back Brace
Anti Shear Left
Anti Shear Right
Pediatric Left Knee
Pediatric Right Knee
Pediatric Shoulder
Pediatric Hip
Upper Extremity Hemiparetic
TREADMILLS
Gait Trainer 3
Gait Trainer Options
Extended Handrails
Pediatric / Geriatric Handrails
Music Assisted Therapy
Music Assisted Therapy (Field Installed)
BALANCE SYSTEMS
New Balance System SD
Biosway Portable Balance System
Balance System Options
Freesway Handles
Vibrotactile System
Vibrotactile Belt Kit XXL
Step Stool
Adjustable Height Biosway Stand
Printer Stand
SUPPORTED AMBULATION SYSTEMS
NxStep Unweighing System
Freestep SAS
Mobility Assist
Supported Ambulation Options
Harness Standard
Harness Bariatric
Harness DLX
Harness Pediatric
Therapist Seat



E04514162



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 8770-5-2023

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

CYCLES

Biostep 2

Upper Body Cycle

-----END OF PRODUCT LIST-----



E04514163