



Certificate No. 5354-2-2020

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

(One Page)

Name of Manufacturer/Distributor, Address

Name of Manufacturer

BIODEX MEDICAL SYSTEMS, INC.
20 Ramsey Rd
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 February 10, 2020 to February 09, 2022.





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

Name of Manufacturer

BIODEX MEDICAL SYSTEMS, INC.
20 Ramsey Rd
Shirley, NY USA 11967

Name of Product(s)

Physical medicine and Physical Rehabilitation Equipment

Biodex System 4

System 4 Pro

System 4 Quick-Set

System 4 MVP

Biodex System Pro

Hamstring Attachment

UE Hemiparetic Attachment

Work Simulation Tools

Anti-Shear Attachment

Pediatric Attachments

Dual Position Back Extension/Flexion Attachment

Reach Attachment

Hip Attachment

Closed Kinetic Chain Attachment

Biodex Gait Trainer 3

Gait Trainer 3

Balance System SD

BioSway

Vibro Tactile System

Unweighting System

NxStep

Sit2Stand

Mobility Assist

FreeStep SAS

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

