



**Certificate No. 6975-3-2022**

**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**

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 March 30, 2022 to March 29, 2024.**





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

**Name of Manufacturer**

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

**Name of Product(s)**

**DOSE CALIBRATORS**

AtomLab 500 Dose Calibrator  
AtomLab 500Plus Dose Calibrator

**THYROID UPTAKE SYSTEMS**

AtomLab 960 Thyroid Uptake System  
AtomLab 960 Thyroid Uptake System with Well Counter

**SURGICAL C-ARM TABLES**

Surgical C-Arm Table 840  
Surgical C-Arm Table 846  
Pain Management C-Arm Table 870  
Urology C-Arm Table 800

Brachytherapy C-Arm Table 810

3D Imaging C-Arm Table 820

**SURGICAL C-ARM TABLES-Accessories**

C-Arm Scatter Radiation Shield  
C-Arm Accessory Clamp

Carbon Fiber Arm Board  
Carbon Fiber Surgical Arm Board

**PAL Stirrups**

Surgical Table Knee Crutch  
Foot Controller

Arm Support Strap

**ULTRA SOUND TABLES**

Sound Pro Combination Table

Ultra Pro Ultrasound Table

Eco Ultrasound Table

Eco Pro Echocardiography Table

Econo Echocardiography Table

Echo/Basc Pro Vascular Echocardiography Table

Vasc Pro Vascular Ultrasound Table

**ULTRASOUND TABLE-Accessories**

Sonography Chair

Foot Controller

Articulating Scanning Arm Board

Folding Side Rails

IV Pole

Paper Dispenser

Retractable Stirrups

Headrest

**MRI STRETCHERS**

MRI Stretcher with Fowler Positioning

MRI Stretcher

Arm Support Strap

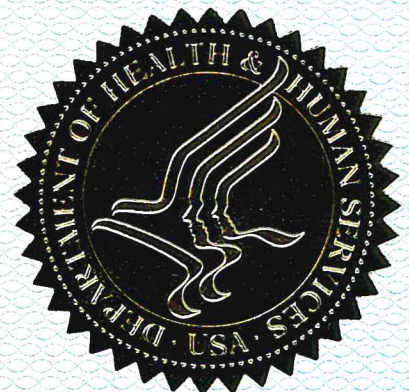
MRI IV Pole

MRI Step Stool

MRI Hamper

**RADIATION SHIELDS**

Clear Lead Mobile Barrier, Standard Window





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