



**Certificate No. 6683-3-2020**

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

(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 10, 2020 to March 09, 2022.**





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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)**

Atomlab 500 Dose Calibrator: 086-330, 086-330-10, 086-332  
Atomlab 960 Thyroid Uptake System: 187-600, 187-601  
Atomlab Wipe Test Counter: 086-331  
Bacteria Filter: 132-750  
Bar Phantom: 243-800, 243-816, 243-935, 243-955, 243-985, 243-987  
C-Arm Table: 058-800, 058-805, 058-810, 058-815, 058-820, 058-825, 058-840, 058-840-10, 058-845, 058-845-10, 058-846, 058-846-10, 058-847, 058-847-10, 058-870, 058-870-10, 058-875, 058-875-10  
Clear-Lead Barrier: 042-580, 042-582, 042-585  
Convenience Kit: 132-680, 132-681, 132-684, 132-690, 132-691, 132-692, 132-699, 132-770, 132-771, 132-774, 132-781, 132-784, 132-793, 134-772, 177-075, 177-091, 177-092, 177-124, 177-324  
Dipper, Syringe: 008-015  
Dipper, Vial/Syringe: 086-242, 086-243  
Drierite: 132-772  
Ultrasound Table: 058-700, 058-701, 058-702, 058-705, 058-706, 058-707, 058-710, 058-715, 058-720, 058-725, 058-726, 058-727, 058-732, 058-733  
Face Mask, Air-Cushioned: 132-685, 132-695, 132-698  
Goggles: 117-425  
L-Block Shield: 042-413, 042-419, 042-433, 042-449  
Lead-Lined Cabinet: 244-009, 244-110, 244-111, 244-112, 244-120, 244-121, 244-122, 244-130, 244-131, 244-132, 244-140, 244-141, 244-142, 244-150, 244-151, 244-152, 244-160, 244-161, 244-162, 244-170, 244-171, 244-172, 244-181, 244-182, 244-190, 244-191, 244-192, 244-200, 244-205  
Lead-Lined Preparation Enclosure: 244-007, 244-008  
Lead-Lined Refrigerator: 244-004, 244-005  
Lead-Lined Storage Safe: 244-006  
MRI Stretcher: 240-100, 240-110  
Niptongs: 011-012, 011-036  
PET Dose Drawing System: 042-466, 042-467  
Pig, Double-Ended: 001-793  
Pig, Unit Dose: 001-280, 001-281, 001-282, 001-785, 001-788, 001-789  
Pig, Shipping Bag: 001-754  
Pig, Vial: 001-706  
Pulmonex II, Xenon System: 132-503  
Radiation Shield: 042-519, 042-522  
Sharps Container Shield: 039-325, 039-326, 039-330, 039-335, 039-338, 039-388, 039-412, 039-413, 039-341, 039-350  
Shield, Bottom: 042-226  
Shield, Gamma: 042-710  
Shield, Lead Glass Plate: 042-228  
Shield, Side: 042-227  
Shield, Tabletop: 042-224  
Shielded Decay Drum: 039-287, 039-288, 039-289  
Shielded Storage Container: 050-200, 050-205, 050-250  
Shielded Syringe Carrier: 001-179, 001-181, 001-180, 001-182  
Shielded Syringe Holder: 009-205  
Shielded Waste Container: 039-106, 039-110  
Shipping Container: 001-723  
Shipping System: 001-692, 001-724, 001-739, 001-786, 001-787, 001-794, 001-822, 001-882, 001-894, 001-921, 001-950  
Soda-Lime: 132-773





**Certificate No. 6683-3-2020**

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

Stand, Dose Preparation: 042-455

Stand, Injection: 135-022

Syringe Shield: 007-612, 007-620, 007-635, 007-652, 007-661, 007-663, 007-665, 007-670, 007-675, 007-680,  
007-685, 007-691, 007-693, 007-695,

007-711, 007-713, 007-716, 007-717, 007-718, 007-723, 007-734, 007-735, 007-736, 007-738, 007-755, 007-  
800, 007-801, 007-900, 007-901, 007-945,

007-956, 007-957, 007-961, 007-962, 007-966, 007-967, 007-969, 007-973, 007-975, 007-980, 007-983, 007-  
984, 007-985, 007-986, 007-990, 007-995

Thyroid Uptake Neck Phantom: 043-365

Venti-Scan IV: 177-090

Vial Shield: 001-236, 001-075, 001-708, 053-610, 053-611, 053-806, 053-807, 001-855

Well Counter: 187-602

Xenon-133 Rebreathing System, Mask: 060-137

Xenon-133 Rebreathing System, Mouthpiece: 060-133

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

