



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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

Certificate No. 8617-3-2018

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.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from March 30, 2018 to March 29, 2020.





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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)

Vial Shields ; 053-610; 053-611; 053-806; 053-806-E; 001-236; 053-805; 001-075; 001-706; 001-708
Sharps Containers
C-Arm Tables: 058-800; 058-810; 058-805; 058-815; 058-820; 058-825;
058-840; 058-845; 058-846; 058-847; 058-870; 058-875; 058-878; 058-886;
058-887; 058-840-10; 058-845-10; 058-846-10; 058-847-10; 058-870-10; 058-875-10
Shielded Storage Containers: 050-200; 050-250; 050-205
L-Block Shields: 042-413; 042-433; 042-419; 042-449
Shielded Shipping Systems: 001-786; 001-787; 001-708; 001-723; 001-724; 001-794; 001-739; 001-822; 001-921; 001-796; 001-894
Shielded Pigs: 001-708; 001-785; 001-788; 001-789; 001-793; 001-280; 001-281; 001-282; 001-798
Syringe Shields: 007-800; 007-900; 007-801; 007-901; 127-735
007-723; 007-734; 007-755; 007-735; 007-736; 007-738; 007-747; 127-734; 127-738; 127-700
007-670; 007-675; 007-680; 007-685; 007-956; 007-957
007-661; 007-663; 007-665; 007-691; 007-693; 007-695; 127-691; 127-693; 127-695
007-620; 007-635; 007-652; 007-612; 007-716; 007-717; 007-718; 007-711; 007-712
007-713; 007-974; 007-945; 007-973; 007-975; 007-980; 007-983; 007-985; 007-990; 007-995; 007-961; 007-962
007-969HSW; 007-966; 007-967; 007-984; 007-986; 127-999; 127-789
Shielded Waste Containers: 039-106; 039-110
Tabletop Shield
Drawing System: 042-466; 042-467;
Entrapping Filter
Aero-Tech II
C-Arm Tables, Basic: 056-025
Venti-Scans: 177-090; 177-091; 177-092; 177-075
Phantoms, Bar: 243-935; 243-800; 243-986; 243-955; 243-975; 243-985; 243-987
Dose Calibrators: 086-330; 086-332; 086-336; 086-331; 075-594; 086-338; 086-509; 086-435; 086-243;
086-423; 086-341; 086-339; 086-334; 086-242; 086-241; 086-343; 086-344; 075-596; 006-350
Lead Glass Goggles: 117-425
Syringe Holders: 009-205; 007-999
Syringe Carriers: 001-181; 001-179; 001-182; 001-180
Ultrasound Tables: 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; 0058-733
Phantom, Neck; 043-365
Phantoms, Flood: 043-054
Thyroid Uptake System: 187-600; 187-601; 187-602; 187-603; 187-146
Mobile Shields: 042-522; 042-519; 042-580; 042-582; 042-585; 042-583
Aero-Tech I: 177-095; 177-124; 177-324; 177-325
Fig Leaf Shield
Atomlab 400 & 500 Dose Calibrators: 086-330; 086-332
MRI Stretcher: 240-100; 240-110
Positioning Wedges: 120-253; 120-274; 120-251; 120-250; 120-280; 120-265; 120-291
Lead Apron: 103-701
MRI Wheelchair
Radiation Resistant Gloves: 208-065; 208-070; 208-075; 208-080; 208-085; 208-090
-----END OF PRODUCT LIST-----

