



Certificate No. 4138-1-2024-1

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

See Attached List

(One Page)

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 January 24, 2024 to January 23, 2026.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.



Certificate No. 4138-1-2024-1

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

Manufacturer

MIRION TECHNOLOGIES (CAPINTEC), INC
7 Vreeland Rd
Florham Park, NJ
USA 07932

Name of Distributor

MIRION TECHNOLOGIES (CAPINTEC), INC
7 Vreeland Rd
Florham Park, NJ
USA 07932

----END OF MANUFACTURER/DISTRIBUTOR LIST----





Certificate No. 4138-1-2024-1

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

Name of Manufacturer

Manufacturer

MIRION TECHNOLOGIES (CAPINTEC), INC
7 Vreeland Rd
Florham Park, NJ
USA 07932

Name of Product(s)

NUCLEAR UPTAKE PROBES
(Thyroid Uptake Systems)
Captus 4000e Thyroid Uptake System, all models
RADIONUCLIDE DOSE CALIBRATORS
CRC-55tR dose calibrator
CRC-55tPET dose calibrator
CRC-55tW dose calibrator
CRC-PC Smart Chamber dose calibrator, all models
CRC-77tHR dose calibrator
RELATED DOSE CALIBRATOR ACCESSORIES
Moly Assay Canister
Mac S Canister
Vial syringe holder (dipper)
Liner, Plexiglas
Tickets
Liner, Copper
Various brachytherapy source holders
SHIELDS, SYRINGE
511 C Tec, all models
Beta Syringe Shield, all models
Pro-Tec II Syringe Shield, all models
Pro-Tec III Syringe Shield, all models
Pro-Tec IV Syringe Shield, all models
Dose Drawing Syringe Shield, all models
High Density Glass Syringe Shield, all models
Pro-Tec PET Syringe Shield, all models
PET, Dose Drawing Syringe Shield, all models
PET Gaard Lock Syringe Shield, all models
Z PET Syringe Shield
Pro-Tec PET MRI Syringe Shield, all models
Pro-Tec Unit Dose Pig, all models
511 Dose Drawing Syringe Shields, all models
Syringe Carriers, large and small, all models
SHIELDS, VIAL
High Density Lead Glass Vial Shield, all models
Lead Vial Shield, all models
Lead Vial Shield with magnetic cap, all models
Tungsten Vial Shield, all models
Tungsten Vial Shield with magnetic cap, all models
511 Vial Shield
Vial Pig, all models
SHIELDS, PERSONNEL
Mobile Radiation Shields, all models
Clear Lead Mobile X-Ray Barriers, all models
PHANTOMS, NUCLEAR ANTHROPOMORPHIC
Neck Phantom
PHANTOM, TEST PATTERN, RADIONUCLIDE
Bar Phantoms, all models
RADIONUCLIDE REBREATHING SYSTEMS
Venti-Scan IV Radioaerosol System





Certificate No. 4138-1-2024-1

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

Venti-Scan IV convenience kits
 AeroTech I Radioaerosol System
 AeroTech I, convenience kits
 TABLE, OPERATING ROOM, AC-POWERED-SURGICAL C-ARM TABLES
 Surgical C-Arm Table 840 and 845 series, all models
 Surgical C-Arm Table 846 and 847 series, all models
 Pain Management C-Arm Table 870 and 875 series, all models
 Urology C-Arm Table 800, all models
 Brachytherapy C-Arm Table 810 series, all models
 3D Imaging C-Arm Table 820 series, all models
 TABLE, AC-POWERED, ULTRASOUND TABLES
 Sound Pro Combination Tables 058-710 and 058-715
 Ultra Pro Ultrasound Tables 058-720 and 058-725
 Eco Ultrasound Table 058-726 and 058-727
 Eco Pro Echocardiography Table 058-700 and 058-705
 Econo Echocardiography Table 058-701 and 058-706
 Echo/Basc Pro Vascular Echocardiography Tables 058-702 and 058-707
 Vasc Pro Vascular Ultrasound Tables 058-732 and 058-733
 STRETCHER WHEELED
 MRI Stretcher
 MRI Stretcher with Fowler Positioning

Name of Distributor

MIRION TECHNOLOGIES (CAPINTEC), INC
 7 Vreeland Rd
 Florham Park, NJ
 USA 07932

Name of Product(s)

PHANTOMS
 Nuclear Test Phantoms
 Radiographic Test Phantoms
 NUCLEAR SEALED CALIBRATION SOURCES
 Flood sources
 Dose calibrator Vial sources
 Rod Sources
 Penpoint markers
 Flexible rulers and markers
 Disk sources
 SHIELDS, PERSONNEL
 Leaded Aprons
 CHAIRS
 Blood Draw/Injection Chairs
 IV STANDS (INFUSION STAND)
 IV Stand, Various Models

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

