



Certificate No. 3930-1-2025-1

CERTIFICATE TO FOREIGN GOVERNMENT

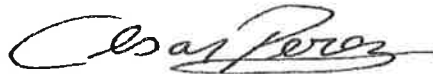
In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	Name of Manufacturer/Distributor, Address
See Attached List (One Page)	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 27, 2025 to January 26, 2027.



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



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

Name of Owner Operator

CODONICS, INC.
17991 ENGLEWOOD DR.
Middleburg Heights, OH
USA 44130

Name of Manufacturer

CODONICS, INC.
17991 Englewood Dr
Middleburg Heights, OH
USA 44130

Name of Distributor

CODONICS, INC.
17991 Englewood Dr
Middleburg Heights, OH
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----END OF MANUFACTURER/DISTRIBUTOR LIST----





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

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Name of Product(s)

CODONICS HORIZON MEDICAL MULTIMEDIA DRY IMAGER

Models/Configurations

Ci Large Format Color, Gray Scale, Film
Ci-RAD Multi Format Color, Gray Scale, Film
Ci-s Medium Format Color, Gray Scale, Film
GS Large Format Gray Scale
GS-RAD Multi Format Gray Scale
GS-s Medium Format Gray Scale
SF Small Format Color, Gray Scale, Film
G (1417) Three Input Single Media
G1 Single Input Multi Format, Gray Scale, Film
G2 Dual Input Multi Format, Gray Scale, Film
XL Medical Long Film Imager (1436 & 1451)

CODONICS SAFE LABELING SYSTEM (SLS)

Models: SLS-1 as SLS-500i/550i/600i, SLS-XXX, Point of Care Station (PCS),
Safe Label System Administration Tool (AT) (all SLS applicable)

DIRECT VISTA THERMAL FILM -FILM RADIOGRAPHIC

Models Various Size Direct Vista Film

Direct Vista Blue Blue Film-8x10, 11x14, 14x17,14x36, 14x51
Direct Vista Blue-T (DVBT) Film-8x10,14x17
Direct Vista Blue-5 (DVB5) Film-8x10, 11x14, 14x17,14x36, 14x51
Direct Vista Clear Film-8x10, 14x17
Direct Vista White Film-A, A4, 11x14, 14x17
Chroma Vista White Film- A, A4

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

