



**Certificate No. 38-10-2023**

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:

<u>Name of Product(s)</u>	<u>Name of Manufacturer/Distributor, Address</u>
See Attached List	See Attached List
(One Page)	(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 October 03, 2023 to October 02, 2025.**





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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.  
Cleveland, OH  
USA 44130

**Name of Distributor**

CODONICS, INC.  
17991 ENGLEWOOD DR.  
Cleveland, OH  
USA 44130

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





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

**Name of Manufacturer**

CODONICS, INC.  
17991 ENGLEWOOD DR.  
Cleveland, OH  
USA 44130

**Name of Distributor**

CODONICS, INC.  
17991 ENGLEWOOD DR.  
Cleveland, OH  
USA 44130

**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-500i/550i, SLS-500P/550P, 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

Virtua Medical Disc Publisher

Models: Virtua, Virtua XR, Virtua C, Virtua E

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

