



**Certificate No. 14339-9-2023**

**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:

**Name of Product(s)**

See Attached List

(One Page)

**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.

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 September 26, 2023 to September 25, 2025.**







**Certificate No. 14339-9-2023**

**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**

**Manufacturer/Manufacturing Facility**

iRay Technology Co. Ltd.  
Rm. 202, Building 7, No.590, Ruiqing Rd.  
Shanghai, Shanghai  
CHINA 201201

**Manufacturer/Manufacturing Facility**

ECOTRON CO LTD  
4F & 5F, Hanshin IT Tower II, 47,  
Digital-ro 9-gil, Geumcheon-Gu  
Seoul, Seoul  
KOREA, SOUTH 08511

**Contract Manufacturer**

IRAY KOREA LIMITED  
1833, 18F, 5, Gasan digital 1-ro, Geumcheon-gu, Seoul,  
Republic of Korea 08594  
Seoul, Seoul  
KOREA, SOUTH 08594

**Name of Manufacturer/Distributor**

**Manufacturer/Manufacturing Facility**

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**

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USA 44130

**Name of Product(s)**

Horizon Multimedia Imager Ci  
Direct Vista Blue Blue Film, Direct Vista Blue-T(DVBT), Direct Vista Blue-5(DVB5); Direct Vi  
Horizon Multimedia Long Film XL Imager  
Mars Version3, 1717v, 1417v  
MARS 1417X CSI DR  
MARS 1717X CSI DR  
EPX Series Mobile X-ray System EPX-F2800, EPX-3200  
MARS 1417X CSI DR  
MARS 1717X CSI DR

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

