



**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](http://www.fda.gov)

**Certificate No. 12438-8-2024-1**

**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

(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 device product(s) may be marketed in, and legally exported from, the United States of America at this time. While the manufacturing plant(s) in which the device product(s) is produced is subject to inspection, FDA does not routinely inspect manufacturing firms that only make Class 1 medical devices. However, the firm has certified that it is currently operating in substantial compliance with current good manufacturing practice requirements for the device 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 August 27, 2024 to August 26, 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](http://www.access.fda.gov/fecv/CDRH).



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**Certificate No. 12438-8-2024-1**

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

**Name of Owner Operator**

Labo America  
920 Auburn Ct  
Fremont, CA  
USA 94538

**Name of Manufacturer**

**Manufacturer/Distributor**

LABO AMERICA  
920 Auburn Ct  
Fremont, CA  
USA 94538

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





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**Name of Manufacturer**

**Manufacturer/Distributor**

LABO AMERICA  
920 Auburn Ct  
Fremont, CA  
USA 94538

**Name of Product(s)**

Atlas 3146100 Vega 3146200 iVu Touch 3146300  
Magna Zoom, Dental Microscope Series  
Prima ENT Microscope Series  
Prima DNT Microscope Series  
Prima Trainer Microscope, 6167500  
Prima OPH Microscope, 6135000-000  
Prima Mu Microscope  
CxL Microscope Series  
Lx Microscope Series  
Luxeo Microscope Series  
Inverted Microscope Series (TCM 400, MET 400)  
Microscope Accessories  
Prima C, 6128000  
Prima CS, 6128100  
Stella Microscope Series  
Prima Lite, ENT Microscope Series  
Prima Lite, Dental Microscope Series  
Prima Pro, Dental Microscope Series  
eVO Microscope Series  
eVA Microscope Series  
Camera Adapter

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





**Certificate No. 12438-8-2024-2**

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**Certificate No. 12438-8-2024-2**

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

**Name of Owner Operator**

Labo America  
920 Auburn Ct  
Fremont, CA  
USA 94538

**Name of Manufacturer**

**Manufacturer/Distributor**

LABO AMERICA  
920 Auburn Ct  
Fremont, CA  
USA 94538

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





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**Name of Manufacturer**

**Manufacturer/Distributor**

LABO AMERICA  
920 Auburn Ct  
Fremont, CA  
USA 94538

**Name of Product(s)**

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Prima ENT Microscope Series  
Prima DNT Microscope Series  
Prima Trainer Microscope, 6167500  
Prima OPH Microscope, 6135000-000  
Prima Mu Microscope  
CxL Microscope Series  
Lx Microscope Series  
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Prima Lite, Dental Microscope Series  
Prima Pro, Dental Microscope Series  
eVO Microscope Series  
eVA Microscope Series  
Camera Adapter

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





**Certificate No. 12438-8-2024-3**

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**Certificate No. 12438-8-2024-3**

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

**Name of Owner Operator**

Labo America  
920 Auburn Ct  
Fremont, CA  
USA 94538

**Name of Manufacturer**

**Manufacturer/Distributor**

LABO AMERICA  
920 Auburn Ct  
Fremont, CA  
USA 94538

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







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USA 94538

**Name of Manufacturer**

**Manufacturer/Distributor**

LABO AMERICA  
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Fremont, CA  
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**Name of Product(s)**

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Camera Adapter

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