

# CERTIFICATE OF REGISTRATION

## Labotron Instruments Pvt Ltd

10 HSIIDC Industrial Estate  
Ambala Cantt, Haryana 133006 INDIA

UL LLC® (UL Solutions) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

### ISO 9001:2015

The design, development, manufacture and servicing of surgical microscopes, slit lamps, optical modules, compound microscopes, stereo microscopes, metallurgical microscopes and inverted microscopes.



Authorized by



**Paul Hilgeman**  
**Senior Business Manager - Medical**  
CMIT – Medical Regulatory



Check Certificate Status:  
[here](#)

File Number A28240  
Certificate Number 1534.240126  
Initial Issue Date July 12, 2018

Cycle Start January 26, 2024  
Effective January 26, 2024  
Expiry Date January 25, 2027

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC® (UL Solutions).



# CERTIFICATE OF REGISTRATION

## Labotron Instruments Pvt Ltd

10 HSIIDC Industrial Estate  
Ambala Cantt, Haryana 133006 INDIA

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**ISO 13485:2016**  
**EN ISO 13485:2016**

The design , development, manufacture and servicing of surgical microscopes, slit lamps and optical modules.



Authorized by



**Paul Hilgeman**  
**Senior Business Manager - Medical**  
CMIT – Medical Regulatory



Check Certificate Status:  
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File Number	A28240	Cycle Start Date	January 26, 2024
Certificate Number	1041.240126	Effective Date	January 26, 2024
Initial Issue Date	January 26, 2018	Expiry Date	January 25, 2027

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UL Solutions  
333 Pfingsten Road  
Northbrook, IL 60062-2096 USA



**Certificate No. 11917-8-2022**

**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. 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 August 05, 2022 to August 04, 2024.**





**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. 11917-S-2022**

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

**Name of Corporate Headquarters**

Labo America  
920 Auburn Ct  
Fremont, CA  
USA 94538

**Name of Manufacturer**

LABOTECH MICROSCOPES INDIA PRIVATE LIMITED  
19, HSIIDC INDUSTRIAL AREA  
AMBALA CANTT, Haryana  
INDIA 133006

**Name of Distributor**

LABO AMERICA  
920 Auburn Ct  
Fremont, CA  
USA 94538

—END OF MANUFACTURER/DISTRIBUTOR LIST—





**Certificate No. 11917-8-2022**

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

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INDIA 133006

**Name of Distributor**

LABO AMERICA  
920 Auburn Ct  
Fremont, CA  
USA 94538

**Name of Product(s)**

SL 45 Microscope  
SL 20/25i Microscope  
Stella N Microscope, 6129200  
Stella Microscope, 6219100  
Atlas 3146100 Vega 3146200 iVu Touch 3146300 Microscope Cameras  
Magna Microscope (Floor), 6129000  
Magna Microscope (Ceiling), 6129001  
Magna Microscope (Wall), 6129002  
Prima ENT Microscope (Basic), 6137000-000  
Prima ENT Microscope (Motorized), 6137000-100  
Prima DNT Microscope (Basic), 6138000-000  
Prima DNT Microscope (Motorized), 6138000-100  
Prima DNT Microscope (Advanced), 6138000-200  
Prima Trainer Microscope, 6167500  
Prima OPH Microscope, 6135000-000  
Prima Mu DNT Microscope, 6211000  
Prima Mu ENT Microscope, 6212000  
CxL Microscope Series  
Lx Microscope Series  
Luxeo Microscope Series  
Microscope Accessories  
eVO 300/350 Microscope, 8126200  
eVO 400/450 Microscope, 8127200  
eVO 500 Microscope, 8145000  
eVA 500 Microscope, 6169000-000  
Prima GN Microscope - 6165000-000  
Prima CS Microscope - 6128100  
Prima C Microscope - 6128000

END OF PRODUCT LIST

