Certificate of Compliance

We hereby declare that the technical file of product complied with the requirement of **Medical Devices Directive (93/42/EEC) & European Directive (2007/47/EC).**

Manufacturer:

Name : APS LAB INSTRUMENTS PRIVATE LIMITED

Address: 142, POCKET-I, SECTOR-3, DSIIDC BAWANA INDUSTRIAL COMPLEX, NEW DELHI - 110039, DELHI, INDIA

Product: As Per Attached Annexure – I

The certification body has performed an audit of the above product quality system covering the design, manufacture and final Inspection of certified product. The quality system has been assessed, approved and is subject to continuous surveillance according **Medical Devices Directive (93/42/EEC) & European Directive (2007/47/EC).**

This certificate issued under the following conditions:

1. It applies only to the quality system maintained in the manufacturing of above referenced models and it does not substitute the design or type examination procedures, if requested
2. The certificate remains valid until the manufacturing conditions or the quality system are changed
3. The certificate validity is conditioned by positive results of surveillance audits
4. After fulfilling relevant EEC legislation, the manufacturer shall affix to each device, of the referenced models The CE mark as shown below can be used under the responsibility of the manufacturer after completion of an EEC Declaration of conformity and compliance with all relevant EEC Directives. The statement is based on a single evaluation of one sample of above mentioned product. Not imply an assessment of the whole production.

:: Certificate No :: CE/25M02157

Date of initial registration:	**30 April 2025**
First Surveillance Audit on or before:	**29 April 2026**
Second Surveillance Audit on or before:	**29 April 2027**
Re-certification Due:	**29 April 2028**

This Certificate is property of MQA and remains valid Subject to satisfactory surveillance audits.

Authorized Signatory

MQA CERTIFICATION SERVICES
130 Thessaly Rd, Nine Elms, London
SW8 5EJ, United Kingdom

UKAF-CB-011

To check validity of the certificate please visit at www.mqacertification.com

Annexure- I

Certificate No :: CE/25M02157

COMPANY NAME:- APS LAB INSTRUMENTS PRIVATE LIMITED

ADDRESS:- 142, POCKET-I, SECTOR-3, DSIIDC BAWANA INDUSTRIAL COMPLEX, NEW DELHI - 110039, DELHI, INDIA

This Certificate refers to above covers the followings products like:

Personnel air shower both sides flow	Bio safety Cabinet
Standard Blood Bank Refrigerator	B.O.D. Incubator
Carbon Dioxide Incubator (CO2 Incubator)	Deep Freezer -20^{0}C TO -40^{0}C
Deep Freezer -40^{0}C TO 086^{0}C	Fume Hood
Hot Air Oven	Incubator
Orbital Shaker	Refrigerator/Vaccine Storage
Laminar Air Flow Horizontal	Freezer Dryer (Lyophilizer)
Mourtuary Refrigerator	Pass Box
Plant Growth Chamber	Table Top Autoclave
Steam Sterilizer Horizontal Cylindrical	Steam Sterilizer Horizontal Rectangular
Steam Sterilizer Vertical	Steam Sterilizer Vertical (High Pressure)
Walk in Cold Room	Environmental Chamber (Cooled Stability Chamber)
Hospital Furniture	ICU Beds
Ward-Care Semi Fowler Beds	Ward-Care Full Fowler Beds
Ward-Care General Beds	Patient Transfer Solutions
Patient Trolleys	Examination Solutions
Examination Table	Ward Care-Bed Side Lockers
Ward Care Solutions	OT Care Solutions
Gynae & Obstetric Solutions	Furniture Mattress
OT Lights	OT Table
Warmer	Surgical Scrub Station
ETO Sterilizer	

Authorized Signatory

MQA CERTIFICATION SERVICES

130 Thessaly Rd, Nine Elms, London
SW8 5EJ, United Kingdom

UKAF-CB-011

To check validity of the certificate please visit at www.mqacertification.com

Certificate of Compliance

This is to certify that

APS LAB INSTRUMENTS PRIVATE LIMITED

142, POCKET-I, SECTOR-3, DSIIDC BAWANA INDUSTRIAL COMPLEX, NEW DELHI - 110039, DELHI, INDIA

Has been assessed by MQA Certification Services and found to be in compliance with meeting the requirements of:

GMP

(Good Manufacturing Practices)

For the Following Activities:

MANUFACTURER AND SUPPLIER OF HORIZONTAL AUTOCLAVE, LABORATORY PULVROZER, DIGITAL PH METER, PLAME PHOTOMETER, MELTING POINT APPARATUS, CIRCULATING LIQID BATH, LAMINAR AIR FLOW, BIOLOGICAL SAFETY CABINET, FUME HOOD, AIR SHOWER, STATIC PASS BOX, AIR CURTAIN, HUMIDITY & TEMPERATURE TEST CHAMBER, SALT SPRAY CHAMBER, SAND & DUST TEST CHAMBER, CARBONATION CHAMBER, STABILITY TEST CHAMBER, PLANT GROWTH CHAMBER, SEED GERMINATOR BOD INCUBATOR, BACTERIOLOGICAL INCUBATOR, ROTARY EVAPORATORS, WATER DISTILLATION UNIT, LYOPHIZER (FREEZER DRYER), LABORATORY DEEP FREEZER, VACCUM OVEN,HOT AIR OVEN, MUFFLE FURNACE, TUBE FURNACE, VARTICAL AUTOCLAVE

:: Certificate No :: GMP/25M02159

Date of initial registration:	**30 April 2025**
First Surveillance Audit on or before:	**29 April 2026**
Second Surveillance Audit on or before:	**29 April 2027**
Re-certification Due:	**29 April 2028**

This Certificate is property of MQA and remains valid Subject to satisfactory surveillance audits.

Authorized Signatory

MQA CERTIFICATION SERVICES
130 Thessaly Rd, Nine Elms, London
SW8 5EJ, United Kingdom

UKAF-CB-011

To check validity of the certificate please visit at www.mqacertification.com

Certificate of Compliance

This is to certify that

APS LAB INSTRUMENTS PRIVATE LIMITED

142, POCKET-I, SECTOR-3, DSIIDC BAWANA INDUSTRIAL COMPLEX, NEW DELHI - 110039, DELHI, INDIA

Has been assessed and certified by MQA Certification Services
As meeting the requirements of:

ISO 13485:2016

(Quality Management Systems for Medical Devices)

For the Following Scope of Activities:

MANUFACTURER AND SUPPLIER OF HORIZONTAL AUTOCLAVE, LABORATORY PULVROZER, DIGITAL PH METER, PLAME PHOTOMETER, MELTING POINT APPARATUS, CIRCULATING LIQID BATH, LAMINAR AIR FLOW, BIOLOGICAL SAFETY CABINET, FUME HOOD, AIR SHOWER, STATIC PASS BOX, AIR CURTAIN, HUMIDITY & TEMPERATURE TEST CHAMBER, SALT SPRAY CHAMBER, SAND & DUST TEST CHAMBER, CARBONATION CHAMBER, STABILITY TEST CHAMBER, PLANT GROWTH CHAMBER, SEED GERMINATOR BOD INCUBATOR, BACTERIOLOGICAL INCUBATOR, ROTARY EVAPORATORS, WATER DISTILLATION UNIT, LYOPHIZER (FREEZER DRYER), LABORATORY DEEP FREEZER, VACCUM OVEN,HOT AIR OVEN, MUFFLE FURNACE, TUBE FURNACE, VARTICAL AUTOCLAVE

:: Certificate No :: MDQMS/25M02160

Date of initial registration:	**30 April 2025**
First Surveillance Audit on or before:	**29 April 2026**
Second Surveillance Audit on or before:	**29 April 2027**
Re-certification Due:	**29 April 2028**

This Certificate is property of MQA and remains valid
Subject to satisfactory surveillance audits.

Authorized Signatory
MQA CERTIFICATION SERVICES
130 Thessaly Rd, Nine Elms, London
SW8 5EJ, United Kingdom

UKAF-CB-011

To check validity of the certificate please visit at www.mqacertification.com

ROYAL ASSESSMENTS PVT. LTD.

MANAGEMENT SYSTEM CERTIFICATE

VERIFIED

www.royalapl.com

This is to certify that

APS LAB INSTRUMENTS PRIVATE LIMITED

142, POCKET-I, SECTOR-3, DSIIDC BAWANA INDUSTRIAL COMPLEX,
NEW DELHI - 110039, INDIA

has been assessed by RAPL and found to comply with the requirements of

ISO 9001 : 2015

Quality Management Systems

For the following activities:

DESIGN, MANUFACTURE, SUPPLY AND SERVICE OF HOSPITAL FURNITURE, ICU & NICU BED, BABY WARMER, LED OT LIGHT, OT LIGHT, OT TABLE, PCR WORK STATION, STEAM STERILIZER (AUTOCLAVE), ETO STERILIZER, DEEP FREEZER, BIOSAFETY CABINET, OVEN, INCUBATOR, BOD INCUBATOR, BLOOD BANK REFRIGERATOR

Certificate Number: E20250522605
Date of certification: 01/05/2025
Ist Surveillance on or before: 30/04/2026
IInd Surveillance on or before: 30/04/2027
Certification Valid Until: 30/04/2028

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

EGAC

Accredited
QMS Certification CAB# 119012

Director (Certification)
Royal Assessments Pvt. Ltd.

623 A, Tower-B, iThum, Plot No. A - 40, Sector - 62, Noida 201301, India.
www.royalapl.com, info@royalapl.com
Phone : +91 120 4251329
This Certificate can be verified at www.iafcertsearch.org

Certificate of Compliance

:: Certificate No :: UG/25M02158

This is to certify that

APS LAB INSTRUMENTS PRIVATE LIMITED

142, POCKET-I, SECTOR-3, DSIIDC BAWANA INDUSTRIAL COMPLEX, NEW DELHI - 110039, DELHI, INDIA

Has been assessed and found to be conforming the requirements of

U.S. FDA

(FDA Regulatory Guideline for Scientific and Medical Instruments)

As Per Attached Annexure – I

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced scope / activities.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed and is subject to continuous surveillance according to the FDA Guidelines
3. The certificate validity is conditioned by positive results or surveillance audits

Validity of this certificate can be verified at www.mqacertification.com

Date of initial registration:	**30 April 2025**
First Surveillance Audit on or before:	**29 April 2026**
Second Surveillance Audit on or before:	**29 April 2027**
Re-certification Due:	**29 April 2028**

This Certificate is property of MQA and remains valid Subject to satisfactory surveillance audits.

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To check validity of the certificate please visit at www.mqacertification.com

Annexure- I

Certificate No :: UG/25M02158

COMPANY NAME:- APS LAB INSTRUMENTS PRIVATE LIMITED

ADDRESS:- 142, POCKET-I, SECTOR-3, DSIIDC BAWANA INDUSTRIAL COMPLEX, NEW DELHI - 110039, DELHI, INDIA

This Certificate refers to above covers the followings products like:

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Carbon Dioxide Incubator (CO2 Incubator)	Deep Freezer -20^{0}C TO -40^{0}C
Deep Freezer -40^{0}C TO 086^{0}C	Fume Hood
Hot Air Oven	Incubator
Orbital Shaker	Refrigerator/Vaccine Storage
Laminar Air Flow Horizontal	Freezer Dryer (Lyophilizer)
Mourtuary Refrigerator	Pass Box
Plant Growth Chamber	Table Top Autoclave
Steam Sterilizer Horizontal Cylindrical	Steam Sterilizer Horizontal Rectangular
Steam Sterilizer Vertical	Steam Sterilizer Vertical (High Pressure)
Walk in Cold Room	Environmental Chamber (Cooled Stability Chamber)
Hospital Furniture	ICU Beds
Ward-Care Semi Fowler Beds	Ward-Care Full Fowler Beds
Ward-Care General Beds	Patient Transfer Solutions
Patient Trolleys	Examination Solutions
Examination Table	Ward Care-Bed Side Lockers
Ward Care Solutions	OT Care Solutions
Gynae & Obstetric Solutions	Furniture Mattress
OT Lights	OT Table
Warmer	Surgical Scrub Station
ETO Sterilizer	

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