

Unique System for Optimal Utilisation of Human Donated Blood



Blood Bank Equipment



Scan this QR Code to
visit our Website

www.authenticinstruments.com



Authentic Instruments

31, Riico Industrial Area, Jhotwara, Jaipur-302012, India

Contact No: 91-9829017100 Email Id: support@authenticinstruments.com

Concept note on certification of medical devices

Mission statements

Blood centre Setting: "To ensure the highest standards of safety and quality in medical devices for blood bank equipment through rigorous compliance with CDSCO certification requirements. We are committed to safeguarding public health by proactively monitoring, evaluating, and certifying devices that meet superior standards. Our goal is to support healthcare providers in delivering safe and effective blood bank services, thereby contributing to the well-being and safety of patients nationwide.

Healthcare Setting: "Committed to excellence in patient care and staff safety, our mission is to uphold the highest standards of indoor air quality within healthcare facilities. We strive to mitigate airborne contaminants, allergens, and pathogens through advanced filtration systems, rigorous monitoring protocols, and continuous improvement initiatives. By prioritizing clean indoor air, we support healing environments and ensure optimal health outcomes for patients and healthcare providers alike."

Regulatory Compliance

Regulatory Compliance and Sustainability: **CDSCO MDR 2017 (MD-5) Overview:** The Medical Device Rules (MDR) of 2017, implemented by the Central Drugs Standard Control Organization (CDSCO) in India, provide the regulatory framework for the manufacture, import, sale, and distribution of medical devices in the country, gazette notified on 2 June 2023. Starting from October 1, 2023, all categories fall under a licensing regime. Any manufacturer or importer intending to sell and distribute medical devices in India must possess a valid license (MD -5) from the Central Drugs Standard Control Organization (CDSCO).

Benefits

*Improved Health and Safety *Reduced Respiratory *Risks Enhanced Infection Control
*Optimized Healing Environment *Enhanced Productivity and Performance
*Improved Cognitive Function *Reduced Sick Days * Ensure compliance with occupational health and safety regulations (OSHA) and healthcare guidelines (CDC, WHO) *Reduced Healthcare Costs *Peace of Mind and Comfort *

Explanatory note

The Indian Medical Device Rules 2017 mark a pivotal moment in the regulation of medical devices in India. By establishing a comprehensive regulatory framework, the MDR 2017 **As blood centres** are required to obtain licenses from CDSCO to operate legally (**in form 28C**), similarly medical device manufacturers producing blood centre equipment must secure licenses before manufacturing and their products for sale in India (**in form MD-5**). Both blood centre equipment Manufacture and the blood centres themselves fall under the licensing regime introduced by Central Drugs Standard Control Organization (CDSCO)

Products manufactured by



under licence regime as per MDR 2017

Blood Bank
Refrigerator
(up to 600 Bags)

Deep Freezer -40°C
(up to 1000 Liter)

Deep Freezer -80°C
(up to 1000 Liter)

Deep Freezer -20°C
(up to 1000 Liter)

Blood Component
Centrifuge
(up to 16 Bags)

Platelet agitator and
incubator
(up to 200 Bags)

Contact Blast
Freezer
(up to 24 Bags)

Blood Collection
Monitor

Blood Bag Tube
Sealer

Double pan Balance

Biological safety
Cabinet Class I (Laminar Air Flow)

Cryo Bath
(up to 12 Bags)

Plasma Thawing
Bath
(up to 12 Bags)

Lab Refrigerator
(up to 1000 Liter)

ML Convertor
(Single Pan balance)

Plasma Expressor

Blood Donor
Couch

Incubator/Hot Air
Oven

Ice Lined
Refrigerator (up
to 600 L)

Central
Monitoring
System

Sterile Connecting
Device

Automatic Plasma
Extractor

Blood Cell
Separator

Bio safety cabinet

CO2 Incubator

BOD Incubator

Lab Centrifuge

Blood Bank

Mother Milk
Bank

Clinical
Microbiology

Air steriliser
corrosion, health

Customer care+91- 9352454200-400, support@authenticinstruments.com

Authentic Instrument Industries Limited

Area of Working: Manufacturing and Supply of Medical, Scientific, Blood banking, Human Milk Banking, Air sterilisation Equipment etc

Introduction: Authentic Instruments is a prominent player in the manufacturing and supply of a wide range of medical cold chain equipment, lab and scientific equipment, and blood bank and milk bank equipment. Established in 1998 by the visionary Mr. Om Prakash Singh, our journey has been marked by a relentless commitment to innovation and excellence. Our dedication to innovation and excellence has established us as leaders in this field.



Mr. O.P. Singh

State-of-the-Art Infrastructure: We have developed a state-of-the-art manufacturing infrastructure that spans across a vast area of 90,000 square feet. This facility is designed according to modern architectural standards, incorporating high-tech machines and advanced technology. This setup allows us to utilize resources efficiently and maintain a high production capacity, enabling us to meet the increasing demands of our clients effectively.

Registered MDR-2017 by indian regularity CDSCO The Central Drugs Standard Control Organisation(CDSCO)under Directorate General of Health Services,Ministry of Health & Family Welfare,Government of India

1. **Development Department:** Focused on continuous research and development to drive innovation.
2. **Manufacturing Unit:** Equipped with advanced machinery to handle high-volume production.
3. **Quality Testing Section:** Dedicated to ensuring that all products meet stringent quality standards.
4. **After Sale service:** Our team of professionals is dedicated to managing these departments with dexterity and expertise. Their commitment ensures that all operations are carried out smoothly and efficiently, maintaining the highest standards of quality and productivity by support of web based self accessed service logs.



Certifications and Compliance

We **Authentic instruments** Our manufacturing site adheres to all mandatory compliances and certifications to manufacture medical equipment as per Government of India rules, ensuring the highest quality and safety standards.

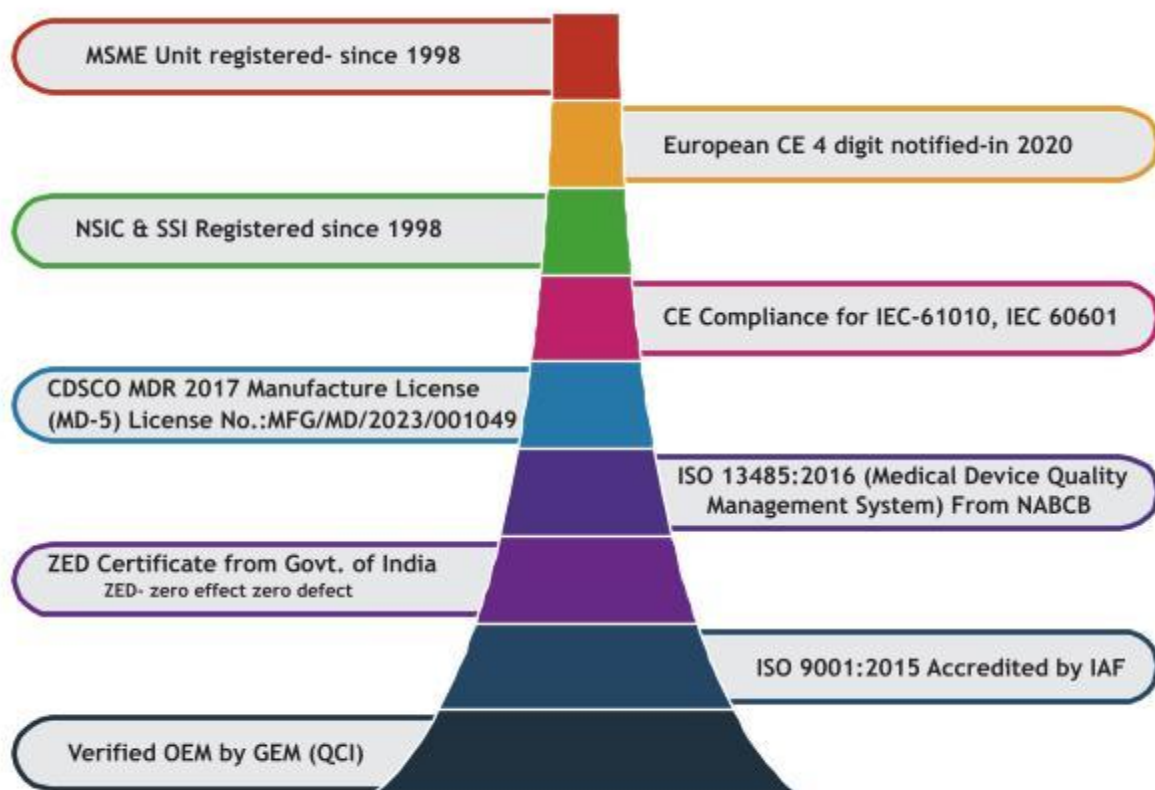
We hold a **Fire Safety NOC**, **Pollution noc Certificate**, and the prestigious **Zero Effect & Zero Defect Certification**.

As a registered **MSME (Micro, Small & Medium Enterprises)** and **SSI (Small Scale Industries) unit**, we are also accredited by **NSIC (National Small Industries Corporation)**.

Our quality management systems are robust, with **ISO 9001 accreditation** by **IAF (International Accreditation Forum)** and **ISO 13485 certification** from **NABCB**.

We meet international safety standards with **CE 4-digit Notified Certification** from the **European Union** and hold **CDSCO licenses** for manufacturing **Class A & B medical devices** as per **MDD 2017 & Electrical Safety Certificates 61010-1 and 60601-1**.

Additionally, we are a verified OEM by **QCI (Quality Council of India)** Vendor Assessment **GEM**.



Scan this QR
Code to visit
our Website



CDSCO MDR 2017 (MD-5) Overview under licence regime since june 2023

CDSCO MDR 2017 (MD-5) Overview: The Medical Device Rules (MDR) of 2017, implemented by the Central Drugs Standard Control Organization (CDSCO) in India, provide the regulatory framework for the manufacture, import, sale, and distribution of medical devices in the country. Starting from October 1, 2023, all categories fall under a licensing regime. Any manufacturer or importer intending to sell and distribute medical devices in India must possess a valid license (MD -5) from the Central Drugs Standard Control Organization (CDSCO).

Making the World Safer, Healthier and More productive

S.no	Certificate Name	Issued By	Valid to	Page No
1	MSME (UDYAM REGISTRATION)	MSME		6
2	price preference certificate	District Industrial & Commerce Centre		8
3	NSIC	NSIC	17/07/23	11
4	CDSCO License MD-5	CDSCO RAJASTHAN		14
5	CE Certificate 4 digit	Technicka inspekcja	23/05/26	19
6	Pollution Certificate	Pollution control board Rajasthan		20
7	Fire Certificate	Fire Department Rajasthan		22
8	SSI	District Industrial Centre		23
9	ZED Bronze	MSME	10/07/26	24
10	CE Compliance	OCV	07/08/24	25
11	ISO 13485	BSCIC	16/11/26	26
12	ISO 9001	AQC MIDDLE EAST	02/12/24	27
13	ISO 9001	ICV ASSESSMENTS PVT. LTD	12/06/27	28
14	WHO-GMP	OCV	15/08/27	29

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भारत सरकार
Government of India
सूक्ष्म, लघु एवं मध्यम उद्यम मंत्रालय
Ministry of Micro, Small and Medium Enterprises



UDYAM REGISTRATION CERTIFICATE

UDYAM REGISTRATION
NUMBER

UDYAM-RJ-17-0016209

NAME OF ENTERPRISE

AUTHENTIC INSTRUMENTS

TYPE OF ENTERPRISE *

SNo.	Classification Year	Enterprise Type	Classification Date
1	2022-23	Micro	26/06/2022
2	2021-22	Micro	16/05/2021
3	2020-21	Small	03/02/2021

MAJOR ACTIVITY

MANUFACTURING

SOCIAL CATEGORY OF
ENTREPRENEUR

GENERAL

NAME OF UNIT(S)

S.No.	Udyog Aadhaar Memorandum	Unit(s) Name
1	RJ17B0025369	Authentic Instruments

OFFICIAL ADDRESS OF
ENTERPRISE

Flat/Door/Block No.	31,Rrico Indl Area	Name of Premises/ Building	Authentic Instruments
Village/Town	jaipur	Block	jhotwara
Road/Street/Lane	31 rilco indl area jhotwara	City	jaipur
State	RAJASTHAN	District	JAIPUR , Pin 302012
Mobile	9314529100	Email:	support@authenticinstruments.com

DATE OF
INCORPORATION /
REGISTRATION OF
ENTERPRISE

20/08/2016

DATE OF
COMMENCEMENT OF
PRODUCTION/BUSINESS

31/01/2002

**NATIONAL INDUSTRY
CLASSIFICATION
CODE(S)**

SNo.	NIC 2 Digit	NIC 4 Digit	NIC 5 Digit	Activity
1	28 - Manufacture of machinery and equipment n.e.c.	2829 - Manufacture of other special-purpose machinery	28299 - Manufacture of other special-purpose machinery n.e.c.	Manufacturing
2	32 - Other manufacturing	3250 - Manufacture of medical and dental instruments and supplies	32502 - Manufacture of laboratory apparatus (laboratory ultrasonic cleaning machinery, laboratory sterilizers, laboratory type distilling apparatus, laboratory centrifuges etc.)	Manufacturing
3	32 - Other manufacturing	3250 - Manufacture of medical and dental instruments and supplies	32505 - Manufacture of measuring instruments such as thermometers etc.	Manufacturing
4	32 - Other manufacturing	3250 - Manufacture of medical and dental instruments and supplies	32509 - Manufacture of other medical and dental instruments n.e.c.	Manufacturing

**DATE OF UDYAM
REGISTRATION**

27/09/2020

* In case of graduation (upward/reverse) of status of an enterprise, the benefit of the Government Schemes will be availed as per the provisions of Notification No. S.O. 2119(E) dated 26.06.2020 issued by the M/o MSME.

Disclaimer: This is computer generated statement, no signature required. Printed from <https://udyamregistration.gov.in> & Date of printing:- 04/05/2023

For any assistance, you may contact:

1. District Industries Centre: JAIPUR URBAN (RAJASTHAN)

2. MSME-DFO: JAIPUR (RAJASTHAN)

Visit : www.msme.gov.in ; www.dcmsme.gov.in ;

s.gov.in



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ions

Government of Rajasthan
OFFICE OF THE DISTRICT INDUSTRIES CENTRE JAIPUR (URBAN)
CERTIFICATE
(SEE CLAUSE 10)

File No. F() PPC/DICC/URBAN/640-641

Date: 17.03.2023

It is certified that **M/s. Authentic Instruments , 31 Jhotwara Industrial Area, Jaipur** was inspected by **Bhuraram Choudhary, Assistant Director of Industries** on dated **16-03-2023** and the facts mentioned by the enterprise are correct as per the record shown by the applicant. The enterprise is eligible for Purchase Preference under this notification. The certificate is valid for one year from the date of its issue .

Office Seal



General Manager
District Industries & Commerce
Centre
Jaipur(Urban)

Enclosure-(1) Application Form
(Part of PPC Certificate)

File No. F() PPC/DICC/URBAN/640-641

Date: 17.03.2023

Copy forwarded to the following for information and necessary action:-

1. The Commissioner of Industries Rajasthan, Jaipur.
2. **M/s. Authentic Instruments , 31 , Jhotwara Industrial Area, Jaipur**

District Industries & Commerce
निता उद्योग एवं वाणिज्य केंद्र जयपुर (शहर)
Jaipur(Urban)

Form

(Apply In Duplicate)

Application By MSME For Price Preference Or Purchase Preference or Both in Procurement Of Goods

To,

The General Manager

DIC, District-Jaipur Rajasthan

1. Name Of Applicant with Post :-Authentic Instruments
2. Permanent Address :-31,Riico Indl Area Jhotwara Jaipur-302012
3. Contact Details :-OM PRAKASH SINGH
 - a. Telephone No:N.A
 - b. Mobile No.:- 9314529100
 - c. Fax No.:
 - d. E- Mail Address :-support@authenticinstruments.com
4. Name of Micro & Small Enterprises:
5. Office Address :-31,Riico Indl Area Jhotwara Jaipur-302012
6. Address Of Work Place :-Jaipur
7. No. & Date Of Entrepreneurs Memorandum-II /UDYOG Aadhaar Memorandum Availed
8. Products For Which Entrepreneurs Memorandum-II /Udyog Aadhaar Memorandum Availed
9. Products For which are at present being produced by the enterprise :
10. Products For Which Price Preference or purchase preference or both has been applied for :

Products
Blood Bank Refrigerator, Blood collection monitor ,bio mixer with battery backup, Deep Freezer,
Donor couch,incubator,bod incubator,oven,laminar air flow, bio safety cabinet fitted with pre-filter & heap filter,
water bath ,environmental test chamber, humidity chamber, Blood Bag Tube Sealer,Refrigrated centrifuge, cryofugel blood component separator m/c ,
Contact Shock freezer, ultra-low deep freezer



1. Production capacity as per capacity Assessment certificate (enclose photocopy of capacity Assessment Certificate)

Serial No.	Product	Production Capacity	
		Quantity	Value
2.	As per NSIC List Attached		
3.			
4.			

For AUTHENTIC INSTRUMENTS

Proprietor

12. List of Plant & Machinery Installed

Serial No.	Name of Plant And Machinery	Quantity	Value
1.	CNC Bending M/C	01	
2.	CNC Shearing M/C	02	
3.	Nothing M/C	01	
4.	Punching M/C	01	
5.	Fiber Lazer Cutting M/C	01	List Attached

13. List Of Testing Equipment's Installed

Serial No.	Name Of Testing Equipment's	Quantity	Value
1.	Tensile Testing M/C	01	
2.	Hardness Tester	04	
3.	Impact Testing M/C	01	
4.	U.T.M	01	List Attached

14. Benefits Availed as per price preference certificate in last financial year and current financial year

a. Benefits Depositing Bid Security and performance Security:

Last Financial Year		Current Financial Year	
Department	Bid Security	Performance Security	Bid Security
NO	NO	NO	NO

b. Details Of Supply Orders Received

Last Financial Year		Current Financial			
Department No.& Date of purchase order	Amount for Which Purchase Order Received	Amount of Goods Supplied	Date Of Purchase Order	Amount For Which Purchase Order Received	Amount of goods supplied

I declare that the above all facts given in the application are correct and my enterprise is producing the items mentioned in Column No.10

Date:

For AUTHENTIC INSTRUMENTS
Proprietor

Signature
Name of Applicant
Along with seal

NSIC



राष्ट्रीय लघु उद्योग निगम लिमिटेड
THE NATIONAL SMALL INDUSTRIES CORPORATION LIMITED

(A Government of India Enterprise)

Sr. No. 127824
S.No. JAI-0091074

Branch Office : NF/0/2, NEHRU PLACE, TONK ROAD, JAIPUR-302015

Ph : 01412742991

Fax : 01412741277

Email : bojal@nsic.co.in Website : www.nsic.co.in

GOVERNMENT PURCHASE ENLISTMENT CERTIFICATE

Renewal Certificate (Valid From 18/07/2023 to 17/07/2025)

Ref.No NSIC/JPR/RAJ/GP/1/1392

Date: 25/07/2023

M/s. Authentic Instruments

31, RIICO Industrial Area, Jhotwara, Near Kamani
Chouraha
JAIPUR,
RAJASTHAN- 302012

Factory Address:

1 .31, RIICO Industrial Area, Jhotwara, Near Kamani
Chouraha
JAIPUR, RAJASTHAN -302012

Name of the Proprietor

Sh. Om Prakash Singh

Constitution: Proprietorship

Udyam Registration

Number UDYAM-RJ-17-
0016209

Enterprise Social Class:

GENERAL

Special Category:

GENERAL

GOVERNMENT PURCHASE REGISTRATION NO: NSIC/GP/JAI/2013/0001198

Monetary Limit: ₹ 227 lakhs (₹ Two Hundred Twenty Seven Lakh Only)

TURNOVER (Rupees in Lakhs)

Financial Year	Annual Turnover
2019-20	221.39
2020-21	202.58
2021-22	454
Monetary Limit	227

MSEs registered with NSIC are exempted from deposit of Earnest Money irrespective of value of Monetary Limit.
Your name has been registered as a MSE Unit eligible for participation in the Central Government Store Purchase
Programme as per the Single Point Registration Scheme for the following Item(s)/Store(s)/Service(s).

Name of the Store(s)/ Service(s)	Specification(s)	Qualitative Capacity	Quantitative Capacity P.M.P.S.
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"As per List Attached" (14 item only)

Disclaimer:-1.The purchasing agencies are advised to satisfy themselves with the store details in the certificate while doing the Technical Evaluation stage before placing the tender/order on the units, certified by NSIC.
2. This certificate will be valid subject to compliance of definition (Composite criteria of investment and turnover for classification of Micro, Small Enterprises as per MSMED Act).



Authorised Signatory

M/s. Authentic Instruments

"Authenticity of the certificate can be checked through the web portal: www.nsicsonline.com"



CIN : U74140DL1955GOI002481

Conditions overleaf.



राष्ट्रीय लघु उद्योग निगम लिमिटेड THE NATIONAL SMALL INDUSTRIES CORPORATION LIMITED

(A Government of India Enterprise)

Sr. No. 199041
S.No. JAI-0001477

Branch Office : NF/0/2, NEHRU PLACE, TONK ROAD, JAIPUR-302015

Ph : 01412742991

Fax : 01412741277

Email : bojal@nsic.co.in Website : www.nsic.co.in

STORE DETAILS CERTIFICATE

Renewal Certificate (Valid From 18/07/2023 to 17/07/2025)

ANNEXURE TO GOVERNMENT PURCHASES ENLISTMENT CERTIFICATE

NO. NSIC/GP/JAI/2013/0001198 D.T. 25/07/2023

ISSUED TO M/s. Authentic Instruments, RAJASTHAN

31, RIICO Industrial Area, Jhotwara, Near Kamani Chouraha, JAIPUR, RAJASTHAN-302012

Sno	Store(s)/ Service(s) Name	Specification(s)	Qualitative Capacity	Quantitative Capacity PMPS	Remarks
1	Blood Bank Refrigerator NIC code: 28299	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS, Compressor + cooling system	50 to 600 bags,	25 Nos. OR	Manufacturer
2	Blood Collection Monitor/Bio mixer with Battery Back up NIC code: 32505	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS, Compressor + cooling system	Up to 900 ml	25 Nos. OR	Manufacturer
3	Deep Freezer NIC code: 32509	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS, Compressor + cooling system	100 to 1000 Liters	25 Nos. OR	Manufacturer
4	Donor Couch NIC code: 28299	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS	Overall Length X Width: 6 x 2	30 Nos. OR	Manufacturer
5	Incubator/BOD Incubator/Hot Air Oven NIC code: 28299	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS, Compressor + cooling system	up to: - 600 Liters	30 Nos. OR	Manufacturer
6	Laminar Air Flow/Bio safety Cabinet fitted with prefilter & hepa filter NIC code: 32509	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS, Compressor + cooling system	Size of Working Table: 2x2x2, 3x2x2, 4x2x2, 6x2x2 Feet	30 Nos. OR	Manufacturer
7	Water Bath/Plasma Thawing	S.S.202/304/316 & MS WITH POWDER COATING,	Up to 400 Liters	40 Nos. OR	Manufacturer

M/s. Authentic Instruments

Authenticity of the certificate can be checked through the web portal: www.nsicspronline.com

CIN : U74140DL1955801002481



Authorised Signatory



राष्ट्रीय लघु उद्योग निगम लिमिटेड THE NATIONAL SMALL INDUSTRIES CORPORATION LIMITED

(A Government of India Enterprise)

Sr. No. 199042
S.No. JAI-0001477

Branch Office : NF/0/2, NEHRU PLACE, TONK ROAD, JAIPUR-302015

Ph : 01412742991

Fax : 01412741277

Email : bojai@nsic.co.in Website : www.nsic.co.in

STORE DETAILS CERTIFICATE

	Bath/Cryo Bath NIC code: 32505	ELECTRICAL ITEMS, Compressor + cooling system			
8	Blood Bank Tube Sealer NIC code: 32509	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS	2 to 6 mm	15 Nos. OR	Manufacturer
9	Environment Test Chamber/Humidity Chamber NIC code: 28299	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS, Compressor + cooling system	Up to 1000 Ltrs	30 Nos. OR	Manufacturer
10	Incinerator NIC code: 28299	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS, Compressor + cooling system	Up to 4 liter/hr.	10 Nos. OR	Manufacturer
11	Refrigerated centrifuge/ cryofuge blood component separator machine NIC code: 32502	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS, Compressor + cooling system	6 to 12 buckets	25 Nos. OR	Manufacturer
12	Contact Shock Freezer/ Blast Freezer NIC code: 32509	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS, Compressor + cooling system	6 to 24 bags	25 Nos. OR	Manufacturer
13	Ultra-Low temperature Deep Freezer NIC code: 32509	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS, Compressor + cooling system	100 to 1000 Liters	30 Nos. OR	Manufacturer
14	Platelet Agitator & incubator NIC code: 32509	S.S.202/304/316 & MS WITH POWDER COATING, ELECTRICAL ITEMS, Compressor + cooling system	10 to 200 bags	25 Nos.	Manufacturer

Comments / Note

(Optional): MSME-DI(J)/NSIC/04/2005-06/4232 dated 27.11.2013 & SGS Inspection Report
No:IN/GUR/IND/NSIC/01973/2019 Dt.23/10/2019 & IN/GUR/IND/NSIC/03997/2023 Dt.21.07.2023

Disclaimer:- "MSEs engaged in Re-packaging, Re-Calibration, Re-sizing, Re-Assembling may need vendor assessment for GeM registration as per their policy."

M/s. Authentic Instruments



Authenticity of the certificate can be checked through the web portal: www.nsicsonline.com

CIN : U74140DL1955GOI002481



Authorised Signatory

CDSO MANUFACTURER LICENSE

**Government of Rajasthan
Food Safety and Drug Control Commissionerate,
Swasthya Bhawan, Tilak Marg, Jaipur- Rajasthan**

Contact no. 0141-2221670

E- mail: drugcontrollerl.mh@rajasthan.gov.in

F NO : RJ/MD/2023/000086

Date : 11/12/2023

To,

M/s Authentic Instruments,
31, RIICO Industrial Area, Jhotwara,
Jaipur, Rajasthan (India) – 302012

Subject: Grant of Licence to Manufacture for Sale and Distribution of
Class A or Class B Medical Device.

Ref.: Your application MFG/MD/2023/87350 Dated 14 Mar., 2023
received at on-line portal of Medical Device of CDSCO.

As applied by you, please find herewith enclosed manufacturing licence granted to you in Form MD-5 to manufacture "Medical Devices" under Drugs & Cosmetics Act, 1940 and Medical Devices Rule, 2017. You shall observe the mandatory requirements of said Act & Rules. You are directed to submit the data of first 3 batches of the products (batch records, certificate of analysis, etc.) which will be treated as trial batches, you shall not sell these products, get these products tested in NABL accredited laboratory and submit the reports.

Competent Technical Staff:-

1. Manufacturing : Mohammed Danish Khan – Manufacturing Chemist
2. Analysis : Sh. Om Prakash Singh – Analytical Chemist


**Drug Controller,
Rajasthan Jaipur**

F NO : RJ/MD/2023/000086

Date : 11/12/2023

Copy to:-

1. Drugs Controller General (India), FDA Bhawan, Kotla Road, New Delhi.
2. Dy. Drugs Controller (India) CDSCO, North Zone, Kamla Nehru Nagar, Ghaziabad.
3. Asstt. Drugs Controller, Jaipur.
4. Concerned file of Manufacturer/Guard File.


**Drug Controller,
Rajasthan Jaipur**



सत्यमेव जयते

FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/MD/2023/001049

1. M/s AUTHENTIC INSTRUMENTS, Plot No. 31, RIICO INDUSTRIAL AREA JHOTWARA, Jaipur, Rajasthan (India) - 302012 Telephone No.: 9314529100 FAX: 9314529100 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Authentic Instruments, 31, Riico Industrial Area, Jhotwara, Jaipur, Rajasthan-302012, Jaipur, Rajasthan (India) - 302012 Telephone No.: 9829017100 FAX: 9314529100

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	<p>Generic Name: Blood storage refrigerator (Blood Bank Refrigerator)</p> <p>Model No.: X1 BBR 50 - To store up to 50 blood bags of 350/450 ml, X1 BBR 100 - To store up to 100 blood bags of 350/450 ml, X1 BBR 150 - To store up to 150 blood bags of 350/450 ml, X1 BBR 200 - To store up to 200 blood bags of 350/450 ml, X1 BBR 300 - To store up to 300 blood bags of 350/450 ml, X1 BBR 400 - To store up to 400 blood bags of 350/450 ml, X1 BBR 500 - To store up to 500 blood bags of 350/450 ml, X1 BBR 600 - To store up to 600 blood bags of 350/450 ml, X2 BBR 50 - To store up to 50 blood bags of 350/450 ml, X2 BBR 100 - To store up to 100 blood bags of 350/450 ml, X2 BBR 150 - To store up to 150 blood bags of 350/450 ml, X2 BBR 200 - To store up to 200 blood bags of 350/450 ml, X2 BBR 300 - To store up to 300 blood bags of 350/450 ml, X2 BBR 400 - To store up to 400 blood bags of 350/450 ml, X2 BBR 500 - To store up to 500 blood bags of 350/450 ml, X2 BBR 600 - To store up to 600 blood bags of 350/450 ml</p> <p>Intended Use: These are devices are intended for medical purposes that are used to preserve blood by storing them at cold temperatures.</p> <p>Class of medical device: Class B</p> <p>Material of construction: MS outerbody powder coated, innerbody SS 304</p> <p>Dimension (if any): External dimension as per model (WxDxH) = 23" x 25" x 46" to 46" x 31" x 80"</p> <p>Shelflife: Nil</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name (if registered for the Trade Mark, 1999): AUTHENTIC</p>



2	<p>Generic Name: Blood storage refrigerator (Deep Freezer (-20C))</p> <p>Model No.: X1 LD 100 - Capacity up to 100 litre, X1 LD 200 - Capacity up to 200 litre, X1 LD 300 - Capacity up to 300 litre, X1 LD 400 - Capacity up to 400 litre, X1 LD 500 - Capacity up to 500 litre, X1 LD 600 - Capacity up to 600 litre, X1 LD 700 - Capacity up to 700 litre, X1 LD 800 - Capacity up to 800 litre, X2 LD 100 - Capacity up to 100 litre, X2 LD 200 - Capacity up to 200 litre, X2 LD 300 - Capacity up to 300 litre, X2 LD 400 - Capacity up to 400 litre, X2 LD 500 - Capacity up to 500 litre, X2 LD 600 - Capacity up to 600 litre, X2 LD 700 - Capacity up to 700 litre, X2 LD 800 - Capacity up to 800 litre</p> <p>Intended Use: These are devices intended for medical purposes that are used to preserve blood products by storing them at freezing temperatures.</p> <p>Class of medical device: Class B</p> <p>Material of construction: MS outer body powder coated, inner SS 304</p> <p>Dimension (if any): External dimension as per model (WxDxH) = 30" x 26" x 52" to 41" x 48" x 80"</p> <p>Shelflife: NIL</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name (if registered under the Trade Marks Act, 1999): AUTHENTIC</p>
3	<p>Generic Name: Blood storage refrigerator (Deep Freezer (-40C))</p> <p>Model No.: X1 DF 100 - Capacity up to 100 litre, X1 DF 200 - Capacity up to 200 litre, X1 DF 300 - Capacity up to 300 litre, X1 DF 400 - Capacity up to 400 litre, X1 DF 500 - Capacity up to 500 litre, X1 DF 600 - Capacity up to 600 litre, X1 DF 700 - Capacity up to 700 litre, X1 DF 800 - Capacity up to 800 litre, X2 DF 100 - Capacity up to 100 litre, X2 DF 200 - Capacity up to 200 litre, X2 DF 300 - Capacity up to 300 litre, X2 DF 400 - Capacity up to 400 litre, X2 DF 500 - Capacity up to 500 litre, X2 DF 600 - Capacity up to 600 litre, X2 DF 700 - Capacity up to 700 litre, X2 DF 800 - Capacity up to 800 litre</p> <p>Intended Use: These are devices intended for medical purposes that are used to preserve blood products by storing them freezing temperatures of upto -40C</p> <p>Class of medical device: Class B</p> <p>Material of construction: MS outer body powder coated, inner body SS 304</p> <p>Dimension (if any): External dimension as per model (WxDxH) = 30" x 26" x 52" to 41" x 48" x 80"</p> <p>Shelflife: NIL</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name (if registered under the Trade Marks Act, 1999): AUTHENTIC</p>
4	<p>Generic Name: Blood storage refrigerator (Deep Freezer (-86C))</p> <p>Model No.: X1 UDF 100 - Capacity up to 100 litre, X1 UDF 200 - Capacity up to 200 litre, X1 UDF 300 - Capacity up to 300 litre, X1 UDF 400 - Capacity up to 400 litre, X1 UDF 500 - Capacity up to 500 litre, X1 UDF 600 - Capacity up to 600 litre, X1 UDF 700 - Capacity up to 700 litre, X1 UDF 800 - Capacity up to 800 litre, X2 UDF 100 - Capacity up to 100 litre, X2 UDF 200 - Capacity up to 200 litre, X2 UDF 300 - Capacity up to 300 litre, X2 UDF 400 - Capacity up to 400 litre, X2 UDF 500 - Capacity up to 500 litre, X2 UDF 600 - Capacity up to 600 litre, X2 UDF 700 - Capacity up to 700 litre, X2 UDF 800 - Capacity up to 800 litre</p> <p>Intended Use: These are devices intended for medical purposes that are used to preserve blood products by storing them at freezing temperatures.</p> <p>Class of medical device: Class B</p> <p>Material of construction: MS outer body powder coated, inner body SS 304</p> <p>Dimension (if any): External dimension as per model (WxDxH) = 26" x 27" x 62" to 38" x 51" x 90"</p> <p>Shelflife: NIL</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name (if registered under the Trade Marks Act, 1999): AUTHENTIC</p>



5	<p>Generic Name: Blood storage refrigerator (Contact shock Freezer)</p> <p>Model No.: X2 CSF 06 - capacity to freeze 06 plasma bags ,X2 CSF 12 - capacity to freeze 12 plasma bags ,X2 CSF 18 - capacity to freeze 18 plasma bags ,X2 CSF 24 - capacity to freeze 24 plasma bags</p> <p>Intended Use: These are devices intended for medical purposes that are used to preserve blood products by storing them at freezing temperatures.</p> <p>Class of medical device: Class B</p> <p>Material of construction: MS outer body powder coated, inner body SS 304</p> <p>Dimension(if any): External dimension as per model (WxDxH) = 34" x 39" x 36" to 42" x 32" x 68"</p> <p>Shelflife: NIL</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): AUTHENTIC</p>
6	<p>Generic Name: Blood bank centrifuge (Blood Bank Centrifuge)</p> <p>Model No.: X1 RC 06 - Capacity to separate 6 blood bag ,X1 RC 08 - Capacity to separate 8 blood bag ,X1 RC 12 - Capacity to separate 12 blood bag ,X1 RC 16 - Capacity to separate 16 blood bag ,X2 RC 06 - Capacity to separate 6 blood bag ,X2 RC 08 - Capacity to separate 8 blood bag ,X2 RC 12 - Capacity to separate 12 blood bag ,X2 RC 16 - Capacity to separate 16 blood bag</p> <p>Intended Use: Intended to separate blood components of a suspension by application of centrifugal force.</p> <p>Class of medical device: Class A</p> <p>Material of construction: MS outer body powder coated, inner body SS 304</p> <p>Dimension(if any): External dimension as per model (WxDxH) = 32" x 42" x 37" to 32.5" x 43" x 36.5"</p> <p>Shelflife: NIL</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): AUTHENTIC</p>
7	<p>Generic Name: Environmental chamber for storage of platelet concentrate (Platelet Agitator & Incubator)</p> <p>Model No.: X1 PIA 20 - Capacity to store 20 platelet bags ,X1 PIA 60 - Capacity to store up to 60 platelet bags ,X1 PIA 120 - Capacity to store up to 120 platelet bags , X1 PIA 200 - Capacity to store up to 200 platelet bags ,X2 PIA 20 - Capacity to store up to 20 platelet bags ,X2 PIA 60 - Capacity to store up to 60 platelet bags ,X2 PIA 120 - Capacity to store up to 120 platelet bags ,X2 PIA 200 - Capacity to store up to 200 platelet bags</p> <p>Intended Use: A refrigerated environmental chamber for storage of platelet concentrate is a device used to hold platelet-rich plasma within a preselected temperature range</p> <p>Class of medical device: Class B</p> <p>Material of construction: MS outer body powder coated, inner body SS 304</p> <p>Dimension(if any): External dimension as per model (WxDxH) = 23" x 25" x 46" to 29" x 25" x 51"</p> <p>Shelflife: NIL</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): AUTHENTIC</p>
8	<p>Generic Name: Blood mixing and blood weighing devices (Blood collection monitor)</p> <p>Model No.: X1 BCM - Weighing Range 0-999gm ,X2 BCM - Weighing Range 0-999gm</p> <p>Intended Use: A blood mixing device is a device intended for medical purposes that is used to mix blood or blood components by agitation. Also intended to weigh blood or blood components as they are collected.</p> <p>Class of medical device: Class A</p> <p>Material of construction: MS outer body powder coated</p> <p>Dimension(if any): External dimension as per model (WxDxH) = 12" x 10" x 10"</p> <p>Shelflife: NIL</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): AUTHENTIC</p>



9	<p>Generic Name: Blood mixing and blood weighing devices (Bucket equalizer)</p> <p>Model No.: DPB-X1 - DIGITAL DISPLAY, DPB-X2 - TOUCH SCREEN DISPLAY</p> <p>Intended Use: Intended to weigh blood or blood component to balance in centrifuge bucket</p> <p>Class of medical device: Class A</p> <p>Material of construction: MS Sheet with powder coated body</p> <p>Dimension (if any): External dimension as per model (WxDxH) = 09" x 10" x 10"</p> <p>Shelflife: NIL</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name (if registered under the Trade Marks Act, 1999): AUTHENTIC</p>
10	<p>Generic Name: Heat-sealing device (Tube Sealer)</p> <p>Model No.: TS-X1 - Seal up to 8 mm blood bag tube</p> <p>Intended Use: A heat-sealing device is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.</p> <p>Class of medical device: Class A</p> <p>Material of construction: MS Sheet with powder coated body</p> <p>Dimension (if any): External dimension as per model (WxDxH) = 6.7"x10.6"x4.5"</p> <p>Shelflife: NIL</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name (if registered under the Trade Marks Act, 1999): AUTHENTIC</p>
11	<p>Generic Name: Class-I biological safety cabinet</p> <p>Model No.: LAF 222 H - SIZE 2X2X2 FEET, LAF 322H - SIZE 3X2X2 FEET, LAF 422H - SIZE 4X2X2 FEET, LAF 622H - SIZE 6X2X2 FEET, LAF 222V - SIZE 2X2X2 FEET, LAF 322V - SIZE 3X2X2 FEET, LAF 422V - SIZE 4X2X2 FEET, LAF 622V - SIZE 6X2X2 FEET</p> <p>Intended Use: Provide a class I biosafety level (BSL) to the operator and the environment during the manipulation of microorganisms and other biological hazardous materials</p> <p>Class of medical device: Class B</p> <p>Material of construction: MS Sheet with powder coated body with SS 304 table</p> <p>Dimension (if any): External dimension as per model (WxDxH) = 26"x 37"x 37" to 50"x 39"x 76"</p> <p>Shelflife: NIL</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name (if registered under the Trade Marks Act, 1999): AUTHENTIC</p>

Place:

Date: 11-Dec-23



23/12/23
 Licensing Authority
 State Licensing Authority
 Drugs Controller
 Rajasthan, Jaipur

CE notified certificate



Technická inšpekcia, a.s.

Trnavská cesta 56, 821 01 Bratislava, Slovenská republika

CERTIFICATE

No.: 1786/1/2023

to technical file of equipment issued according of EN ISO/IEC 17020

Date of issue: 23th May 2023

Name of equipment: BLOOD STORAGE REFRIGERATOR, models: X1 BBR-50, X1 BBR-80, X1 BBR-150, X1 BBR-200, X1 BBR-300, X1 BBR-400, X1 BBR-500, X1 BBR-600, X2 BBR-50, X2 BBR-80, X2 BBR-150, X2 BBR-200, X2 BBR-300, X2 BBR-400, X2 BBR-500, X2 BBR-600
ULTRA DEEP FREEZER (UP TO -80°C), models: X1 UDF-100, X1 UDF-200, X1 UDF-300, X1 UDF-400, X1 UDF-500, X1 UDF-600, X1 UDF-700, X1 UDF-800, X2 UDF-100, X2 UDF-200, X2 UDF-300, X2 UDF-400, X2 UDF-500, X2 UDF-600, X2 UDF-700, X2 UDF-800
DEEP FREEZER (UP TO -40°C), models: X1 DF-100, X1 DF-200, X1 DF-300, X1 DF-400, X1 DF-500, X1 DF-600, X1 DF-700, X1 DF-800, X2 DF-100, X2 DF-200, X2 DF-300, X2 DF-400, X2 DF-500, X2 DF-600, X2 DF-700, X2 DF-800
CONTACT SHOCK/BLAST FREEZER, models: X2 CSF-06, X2 CSF-12, X2 CSF-16, X2 CSF-24
BLOOD BANK COMPONENT CENTRIFUGE, models: X1 RC-06, X1 RC-08, X1 RC-12, X1 RC-16, X2 RC-06, X2 RC-08, X2 RC-12, X2 RC-16

Manufacturer: AUTHENTIC INSTRUMENTS
Address: 31, RIICO INDUSTRIAL AREA, JHOTWARA, JAIPUR, RAJASTHAN, INDIA, 302012

Applicant: See manufacturer


Basis for certificate issuing: Inspection report No. 1786/1/2023

Applicable standards: IEC 61010-1:2010

After evaluation of submitted documentation of equipment (TCF) in accordance with Directive 2014/35/EU, Technická inšpekcia, a. s. issues this

certificate

the technical file of equipment fulfills safety requirements and it is in accordance with Low Voltage Directive 2014/35/EU.

The manufacturer may indicate compliance to this directive by signing EU declaration of conformity himself according Article 15 of this directive and applying the CE marking  to the equipment according to Article 16 and 17 of this directive.

The manufacturer will inform Technická inšpekcia, a.s. about every modification that can affect safety of the equipment.

This certificate is valid to 23th May 2026

Bratislava, 23th May 2023



On behalf of Technická inšpekcia, a.s.

Ing. Jozef Kamzik
Director of Regional office Bratislava

INDIA Representative:  TARGET CONFORMITY MANAGEMENT SERVICES. For any questions use www.tcmservices.net

CERT-058

4 notified body nos 1354, website where this certificate shown
https://ec.europa.eu/growth/single-market/ce-marking_en and who is
issued to authentic ce certification website www.tisr.sk/en, this
information is provided by authentic



A 015243



Regional Office Jaipur
Rajasthan State Pollution Control Board
Opp. Road No 5, VKIA, Sikar Road, Jaipur
Phone: 0141-2332263



Registered

File No : F(Tech)/JAIPUR(Jaipur(VKIA))/6968(1)/2023-2024/1099-1100

Order No : 2023-2024/Jaipur/12095

Dispatch Date: Jul 14 2023 9:13PM

Unit Id : 125949

M/s AUTHENTIC INSTRUMENTS

31, INDUSTRIAL AREA, JHOTWARA, JAIPUR-302012,
JHOTWARA Tehsil:Jaipur(VKIA)

District:JAIPUR

Sub: **Consent to Establish** under Section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and under Section 21(4) of Air (Prevention & Control of Pollution) Act, 1981.

Ref: Your application(s) for Consent to Establish dated 22/03/2023 and subsequent correspondence.

Sir,

Consent to Establish under the provisions of Section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 (hereinafter to be referred as the Water Act) and under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981, (hereinafter to be referred as the Air Act) as amended to date and rules & the orders issued thereunder **is hereby granted** for your **INDUSTRY plant** situated / proposed at **31, INDUSTRIAL AREA, JHOTWARA, JAIPUR-302012 JHOTWARA Tehsil:Jaipur(VKIA) District:JAIPUR**, Rajasthan under the provisions of the said Act(s). This consent is granted on the basis of examination of the information furnished by you in consent application(s) and the documents submitted therewith, subject to the following conditions:-

- 1 That this Consent to Establish is valid for a period from **22/03/2023** to **29/02/2028** or **date of commencement of production / commissioning of the project or activities whichever is earlier**.
- 2 That this Consent is granted for manufacturing / producing following products / by products or carrying out the following activities or operation/processes or providing following services with capacities given below:

Particular	Type	Quantity / Capacity
FABRICATION OF MEDICAL DEVICES AND LAB EQUIPMENTS	Product	5,000.00 NOS. PER YEAR

- 3 That in case of any increase in capacity or addition / modification / alteration or change in product mix or process or raw material or fuel, the project proponent is required to obtain fresh consent to establish.

Signature Not Verified

Digitally signed by Vijay Sharma
Date: 2023.07.14 21:13:18 IST
Reason: Self Attested
Location:





Regional Office Jaipur
Rajasthan State Pollution Control Board
Opp. Road No 5, VKIA, Sikar Road, Jaipur
Phone: 0141-2332263



Registered

File No : F(Tech)/JAIPUR(Jaipur(VKIA))/6968(1)/2023-2024/1101-1102

Order No : 2023-2024/Jaipur/12096

Date: Jul 14 2023 9:13PM

Unit Id : 125949

M/s AUTHENTIC INSTRUMENTS

31, INDUSTRIAL AREA, JHOTWARA, JAIPUR-302012 ,
JHOTWARA Tehsil:Jaipur(VKIA)
District:JAIPUR

Sub: **Consent to Operate** under Section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 and under Section 21(4) of Air (Prevention & Control of Pollution) Act, 1981.

Ref: Your application for Consent to Operate dated 22/03/2023 and subsequent correspondence.

Sir,

Consent to Operate under the provisions of Section 25/26 of the Water (Prevention & Control of Pollution) Act, 1974 (hereinafter to be referred as the Water Act) and under Section 21 of the Air (Prevention & Control of Pollution) Act, 1981, (hereinafter to be referred as the Air Act) as amended to date and rules & the orders issued thereunder **is hereby granted** for your **INDUSTRY plant** situated at **31, INDUSTRIAL AREA, JHOTWARA, JAIPUR-302012 JHOTWARA Tehsil:Jaipur(VKIA) District:JAIPUR**, Rajasthan, subject to the following conditions:-

- 1 That this Consent to Operate is valid for a period from **22/03/2023** to **28/02/2033**.
- 2 That this Consent is granted for manufacturing / producing following products / by products or carrying out the following activities or operation/processes or providing following services with capacities given below:

Particular	Type	Quantity with Unit
FABRICATION OF MEDICAL DEVICES AND LAB EQUIPMENTS	Product	5,000.00 NOS. PER YEAR

- 3 That this Consent to Operate is for existing plant, process & capacity and separate Consent to Establish/Operate is required to be taken for any addition / modification / alteration in process or change in capacity or change in fuel.
- 4 That the quantity of effluent generation along with mode of disposal for the treated effluent shall be as under:

Signature Not Verified

Digitally signed by Vijay Sharma
Date: 2023.07.14 21:13:58 IST
Reason: SelfAttested
Location:



नगर निगम, जयपुर ग्रेटर

(राजस्थान नगरपालिका अधिनियम 2009 की धारा के अन्तर्गत)

Fire NOC

अनापत्ति प्रमाण पत्र

आवेदन नं.: LSG/JAIPUR GREATER/FIRENOC/2023-24/19543
जारी दिनांक: 05-JUL-2023

प्रेषित-

आवेदक का नाम श्री/श्रीमती: OM PRAKASH SINGH
आवेदक का पता: B 425 MURLIPURA SCHEME MURLIPURA JAIPUR

विषय:- अग्निशमन अनापत्ति प्रमाण पत्र जारी करने बाबत

आपके भवन AUTHENTIC INSTRUMENTS, 31, JHOTWARA INDUSTRIAL AREA, JHOTWARA, JAIPUR GREATER, JAIPUR, RAJASTHAN का निरीक्षण किया गया निरीक्षण के दौरान अग्नि सुरक्षा उपकरण सही पाए गए अतः उपरोक्त सुरक्षा व्यवस्था के अनुसार निम्न शर्तों पर पाबंद करते हुए यह स्थाई (Permanent) अनापत्ति प्रमाण पत्र जारी किया जाता है।

शर्त:-

- अनापत्ति प्रमाण पत्र जारी करने कि तिथि से एक वर्ष कि अवधि हेतु ही मान्य होगा। एक वर्ष बाद अनापत्ति प्रमाण पत्र का नवीनीकरण किया जाना आवश्यक होगा, अन्यथा अनापत्ति स्वतः निरस्त मानी जावेगी।
- भवन के समस्त स्टाफ व सिक्योरिटी गार्ड्स को वर्ष में कम से कम दो बार अग्निशमन विभाग द्वारा प्रशिक्षण दिलाना आवश्यक होगा।
- अग्निशमन उपकरण समयावधि में रीफिल कराना होगा।
- निरीक्षण के दौरान आवश्यक दिशा निर्देशों का पालन करना आवश्यक होगा।
- यदि राज्य सरकार या निगम द्वारा भविष्य में कोई नियम/उपनियम जारी किया जाता है तो प्रबंधक को मान्य होगा।
- भवन का मुख्य अग्निशमन अधिकारी द्वारा कभी भी निरीक्षण किया जा सकेगा व फायर सिस्टम कार्यरत नहीं पाए जाने कि स्थिति में यह अभिशंषा पत्र निरस्त माना जाएगा।
- पानी के टैंक हर समय भरे रखने होंगे व पम्प व पूरा फायर सिस्टम 24 घण्टे कार्यशील स्थिति में रखने को बाध्य होंगे।
- फायर सिस्टम को चलाने हेतु 24 घंटे फायर प्रशिक्षित कर्मचारी रखने होंगे तथा ए एम सी करवायी जाकर सिस्टम का रख रखाव व संचालन करना अनिवार्य होगा।
- फायर वाहन आसानी से आ जा सके इसके लिए पर्याप्त खुला स्थान अवरोध रहित रखना होगा।
- भवन के अंदर किसी भी प्रकार का विस्फोटक पदार्थ व अति ज्वलनशील पदार्थ नहीं रखा जावे।
- रोप लेडर व दो रस्सा भवन के सभी टावर में टावर कि उंचाई जितना हर समय भवन में रखना होगा।
- यह अग्नि सुरक्षा प्रमाणपत्र अग्नि सुरक्षा की दृष्टि से ही मान्य होगा।
- भूमि व भवन संबंधित किसी भी प्रकार के विवाद हेतु यह पत्र बतौर साक्ष्य मान्य नहीं होगा एवं इस बाबत आवेदक स्वयं उत्तरदायी होगा।
- यह अनापत्ति प्रमाण पत्र रूफटॉप रेस्टोरेट के लिए मान्य नहीं हैं। जिस भाग के लिए अनापत्ति प्रमाण पत्र जारी किया जा रहा है वहा पर रूफटॉप रेस्टोरेट का संचालन पूर्णतया प्रतिबंधित रहेगा।

अग्निशमन अधिकारी
नगर निगम, जयपुर ग्रेटर



Signature Not Verified

Digitally signed by Santa
Designation : DC/EO/Commissioner
Date: 2023.07.05 23:16:22 IST
Reason: Approved

GOVERNMENT OF RAJASTHAN
DISTRICT INDUSTRIES CENTRE
JAIPUR (URBAN)



1. Name of Unit :

Constitution of the Unit :

Office Address :

DVUSI

4. Machinery

Value then Rs. 1 Lakh.

4. Factory Location :

M/s. Authentic Instruments

Raj.

B-425 Multipurpose Scheme Jaipur

12-14 Bhadani Niketan Vistar New
Vishnu Sahani Chokra Jaipur

Block Code 10000000				District Code	1	3	State Code	1	7
------------------------	--	--	--	---------------	---	---	------------	---	---

Valid for Five Years

PERMANENT REGISTRATION CERTIFICATE

5. The above unit is permanently registered for the manufacture of item/activities as stated in the Application Form and briefly noted below :

- (1) Lab Equipments
- (2)
- (3)
- (4)

W/C CODE

6. Investment in Plant and Machinery :
Rs. in 000

6/0/7/6

7. Permanent Registration No

17/13/01/2427/FMT/SSI

8. Date of Issue :

31/01/2003

9. Date of Commencement of Production :

02/11/2002

10. Category of Unit :

सहायक निदेशक
विद्युत उद्योग विभाग, जयपुर
REGISTERING AUTHORITY

Note: Terms & conditions as overleaf :

P. T. O.

ZERO EFFECT & ZERO DEFECT CERTIFICATE



सूक्ष्म, लघु और मध्यम उद्यम मंत्रालय
MINISTRY OF
MICRO, SMALL &
MEDIUM ENTERPRISES



CERTIFICATE

ZED BRONZE

under MSME Sustainable (ZED) Certification Scheme
awarded to

Authentic Instruments

UNIT NAME

Flat No:- 31 Riico Indl Area, Building:- Authentic Instruments, Road/Street:- Jhotwara,
Village/Town:- 31,Riico Indl Area jhotwara, Block:- , City:- Jaipur, JAIPUR, RAJASTHAN-
302012

UNIT ADDRESS

32-Other manufacturing

CODE (AS PER NIC-2008)

UDYAM-RJ-17-0016209

UDYAM REGISTRATION NUMBER

Issued on :
July 11, 2023

Certificate Validity :
Three years from the date of issue



Certificate No. 11072023 046350

This Certificate has been awarded after fulfilling all relevant requirements as laid down in the
MSME Sustainable (ZED) Certification Scheme Guidelines for this Certification Level.
Award of this Certificate does not substitute any legal requirement needed for setting up or operating an MSME Unit.

CE Compliance



Certificate of Compliance

We hereby declare that the technical file of all the items in each product group complies with the requirement of Directive Medical Devices Regulation (EU) 2017/45-MDR Class -2

Manufacturer

Name : **AUTHENTIC INSTRUMENTS**
Address : **31, RIICO INDUSTRIAL AREA, JHOTWARA, JAIPUR-302012,
RAJASTHAN, INDIA**
Product : **PRODUCTS DETAILS AS PER APPENDIX 1 & 2**

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 surveillance according to Directive Medical Devices Regulation (EU) 2017/45-MDR Class -2

This certificate issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture 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 not changed
3. The certificate validity is conditioned by positive results of surveillance audits

The CE mark as shown above 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. It does not imply an assessment of the whole production

Date of Certification: 08th August 2024
1st Surveillance Date: 07th July 2025

2nd Surveillance Date: 07th July 2026
Certificate Expiry Date: 07th August 2027
(Subject to the company maintaining its system to the required standard)

Certificate Number: CE-8458

Validity of this certificate can be verified at www.ocicert.in

Authorised Signatory





Certificate of Compliance

APPENDIX - I

The appendix shall be an integral part of the certificate, all expressions and terms defined or used in the certificate shall have the same meaning in this addendum, unless the context clearly required otherwise

MEDICAL EQUIPMENTS NAME

S.no	Equipment Name	Model
1	Blood Donor Couch	X1 DCM, X2 DCM
2	Blood Storage Refrigerator/Blood Bank Refrigerator (up to 600 bag)	X1 BHR 50,X1 BHR 80,X1 BHR 150,X1 BHR 200,X1 BHR 300,X1 BHR 400,X1 BHR 500,X1 BHR 600,X2 BHR 50,X2 BHR 80,X2 BHR 150,X2 BHR 200,X2 BHR 300,X2 BHR 400,X2 BHR 500,X2 BHR 600
3	Laboratory Deep Freezer/Deep Freezer -20°C (Up to 1000 L)	X1 LD 100,X1 LD 200,X1 LD 300,X1 LD 400,X1 LD 500,X1 LD 600,X1 LD 700,X1 LD 800,X1 LD 900,X1 LD 1000,X2 LD 100,X2 LD 200,X2 LD 300,X2 LD 400,X2 LD 500,X2 LD 600,X2 LD 700,X2 LD 800,X2 LD 900,X2 LD 1000
4	Deep Freezer -40°C (Up to 1000 L)	X1 DF 100,X1 DF 200,X1 DF 300,X1 DF 400,X1 DF 500,X1 DF 600,X1 DF 700,X1 DF 800,X1 DF 900,X1 DF 1000,X2 DF 100,X2 DF 200,X2 DF 300,X2 DF 400,X2 DF 500,X2 DF 600,X2 DF 700,X2 DF 800,X2 DF 900,X2 DF 1000
5	Ultra-Low Temperature Deep Freezer -86°C / Deep Freezer -86°C (Up to 1000 L)	X1 UDF 100,X1 UDF 200,X1 UDF 300,X1 UDF 400,X1 UDF 500,X1 UDF 600,X1 UDF 700,X1 UDF 800,X1 UDF 900,X1 UDF 1000,X2 UDF 100,X2 UDF 200,X2 UDF 300,X2 UDF 400,X2 UDF 500,X2 UDF 600,X2 UDF 700,X2 UDF 800,X2 UDF 900,X2 UDF 1000
6	Blood Collection Monitor	X1 BCM, X2 BCM
7	Tube Sealer	X1-TS
8	Centrifuge Bucket Equalizer/Rotor Balance	DPB X1, DPB X2
9	Class I Biological Safety Cabinet (Laminar air flow)/Air Sterilizer	LAF 622H,LAF422H,LAF 322H,LAF 222H,LAF 622V,LAF422V,LAF 322V,LAF 222V, X1-AS 01,X1-AS 02,X1-AS 01, X2 AS 01, X2-AS 02,X2-AS 03
10	Class II Biological Safety Cabinet (Biosafety Cabinet Type A2/B2)	BSC 322H,BSC 422H,BSC 622H
11	Platelet Agitator & Incubator	X1 PIA 20, X1 PIA 60, X1 PIA 120, X1 PIA 200,X2 PIA 20, X2 PIA 60, X2 PIA 120, X2 PIA 200
12	Contact Shock/Blast freezer	X2 CSF 06, X2 CSF 12, X2 CSF 18, X2 CSF 24
13	Blood Bank Centrifuge/Refrigerated Blood Component Centrifuge (Up to 16 bag)	X1 RC 06, X1 RC 08, X1 RC 12, X1 RC 16,X2 RC 06, X2 RC 08, X2 RC 12, X2 RC 16
14	Refrigerated Centrifuge	X1 LRC 08, X1 LRC 12, X1 LRC 24, X1 LRC 36, X2 LRC 08, X2 LRC 12, X2 LRC 24, X2 LRC 36
15	Lab Centrifuge	X1 LC 10, X1 LC 20, X1 LC 30, X1 LC 40, X2 LC 10, X2 LC 20, X2 LC 30, X2 LC 40
16	Plasma Thawing Bath	X1 PTB 12, X2 PTB 12

Certificate Number: CE-8458



Validity of this certificate can be verified at www.ocicert.in

Authorised Signatory



Validity of this Certificate is subject to successful Annual Surveillance audits to be done. This certificate is the property of Optimum Certifications Inc. and shall be returned immediately upon request. Optimum Certifications Inc. is Accredited by UKSAF (www.uksaf.org.uk) Suite 19, Regent Court, 70 West Regent Street, Glasgow, Scotland, G2 2QZ



Certificate of Compliance

APPENDIX - II

The appendix shall be an integral part of the certificate, all expressions and terms defined or used in the certificate shall have the same meaning in this addendum, unless the context clearly required otherwise

MEDICAL EQUIPMENTS NAME

17	Refrigerated Water Bath / Cryo Bath	X1 CB 12, X2 CB 12
18	Serology Water Bath	AI-SWB
19	Incubator	AI-101, AI-102, AI-103
20	Hot Air Oven	AI-101H, AI-102H, AI-103H
21	ML Convertor / Single Pan balance	X1 SPB, X2 SPB
22	Central Monitoring System	X2 CMS
23	BOD Incubator (up to 600 L)	X1 BOD 100, X1 BOD 200, X1 BOD 300, X1 BOD 400, X1 BOD 500, X1 BOD 600, X2 BOD 100, X2 BOD 200, X2 BOD 300, X2 BOD 400, X2 BOD 500, X2 BOD 600
24	CO2 Incubator (up to 600 L)	X1 CO 100, X1 CO 200, X1 CO 300, X1 CO 400, X1 CO 500, X1 CO 600, X2 CO 100, X2 CO 200, X2 CO 300, X2 CO 400, X2 CO 500, X2 CO 600
25	Lab Refrigerator / kit Refrigerator (up to 600 L)	X1 LR 100, X1 LR 200, X1 LR 300, X1 LR 400, X1 LR 500, X1 LR 600, X2 LR 100, X2 LR 200, X2 LR 300, X2 LR 400, X2 LR 500, X2 LR 600
26	Mortuary Chamber/Freezer (up to 12 body)	AI-MC 02, AI-MC 04, AI-MC 06, AI-MC 08, AI-MC 10, AI-MC 12
27	Ice Lined Refrigerator (up to 600 L)	X1 ILR 100, X1 ILR 200, X1 ILR 300, X1 ILR 400, X1 ILR 500, X1 ILR 600, X2 ILR 100, X2 ILR 200, X2 ILR 300, X2 ILR 400, X2 ILR 500, X2 ILR 600
28	Plasma Expressor	PE-01
29	Tube stripper	AI-TS
30	Vdrt/Rotaryshaker	AI-VRS
31	Portable Donor Chair	AI-PDC
32	Milk Pasteurizer	AI-MP 01, AI-MP-02,
33	Milk Lyophilizer	AI-MDL-001, AI-MDL-002
34	Blood Transportation refrigerator	X1 BTR 20, X1 BTR 40, X1 BTR 60, X1 BTR 80

Certificate Number: CE-8458



Validity of this certificate can be verified at www.ociert.in

Authorised Signatory





BSCIC

Certificate

MEDICAL DEVICE -
QUALITY MANAGEMENT SYSTEM

This is to certify that:

AUTHENTIC INSTRUMENTS

31, RIICO INDUSTRIAL AREA, JHOTWARA, JAIPUR - 302 012
RAJASTHAN, INDIA

Hereby granted the Certificate Number: **BN22546/21470**

Rev. 00

Subsequent to the Assessment of the organization, it has been found to be operating a Medical Device-Quality Management System which complies with the requirements of

ISO 13485:2016

For the following scope:

Design, Manufacture, Servicing & Supply of Blood Bank Refrigerator, Deep Freezer(-20°C), Deep Freezer(-40°C), Deep Freezer(-86°C), Contact Shock Freezer, Blood Bank Centrifuge, Platelet Agitator & Incubator, Blood Collection Monitor, Tube Sealer, Class 1 Biological Safety Cabinet, Bucket Equalizer

Technical area:- Active (Non-Implantable) Medical Devices other than Specified Above A.1.2.21

For
BSCIC CERTIFICATIONS PVT.LTD.

Originally Registered:	17-Nov-2023	1st Surveillance Due on:	16-Nov-2024
Issue Date:	17-Nov-2023	2nd Surveillance Due on:	16-Nov-2025
Expiry Date:	16-Nov-2026		

Sapray Seth
Managing Director

(In case if Surveillance Audit is not allowed to be conducted; this Certificate shall be Suspended/Withdrawn).

Please Re-validate this certificate's status at www.bscic-icc.com at REGISTRATION STATUS.
This Certificate of Registration is granted subject to relevant provisions of the BSCIC Certifications PVT. LTD. Contract Terms & Scheme for Registration Form B015 (Latest Version). Please see B015 at our website www.bscic-icc.com.
The certificate of Registration remains the property of BSCIC Certifications Pvt. Ltd. and shall be returned immediately upon request.
BSCIC Headquarters: A-Work, 1st Floor, 58/15A, Crown Plaza Mall, Faridabad - 121 007, Haryana, India

Page 1 of 1

Registered



QM 030

Certificate of Registration

This is to Certify that
Quality Management System of

AUTHENTIC INSTRUMENTS

31, INDUSTRIAL AREA, JHOTWARA, JAIPUR -302012
(RAJASTHAN) INDIA.

has been assessed and found to conform to the requirements of

ISO 9001:2015

for the following scope :

MANUFACTURE, MARKETING, SUPPLY, EXPORTS AND AFTER SALES SERVICE
OF SCIENTIFIC & LABORATORY EQUIPMENT & INSTRUMENTS, BLOOD BANK
EQUIPMENTS, HOSPITAL EQUIPMENTS AND STERILIZATION EQUIPMENTS.

Certificate No	: 21IQJD41	
Initial Registration Date	: 03/12/2021	Issuance Date : 03/12/2021
Date of Expiry	: 02/12/2024	
1st Surve. Due	: 03/11/2022	2nd Surve. Due : 03/11/2023


Director



ACCREDITED
Management Systems
Certification Body
MSCB-119



AQC MIDDLE EAST LLC

Head Office: Office No. 02, Ground Floor, Sharjah Media City, Sharjah, UAE. e-mail : info@aqcworld.com.

Key Location: A-60, Sector - 2, Noida, Uttar Pradesh, 201301, India.

*Validity of the Certificate is subject to successful completion of surveillance audit on or before of due date. (in case surveillance audit is not allowed to be conducted, this certificate shall be suspended/withdrawn).

Certificate Verification: Please Re-check the validity of certificate at <http://www.aqcworld.com/activeclients.aspx> or www.aqcworld.com at Active Clients.
Certificate is the property of AQC Middle East LLC and shall be returned immediately when demanded



ISO 9001 Accredited



Certificate of Registration

This Certificate certify that the Management System of

AUTHENTIC INSTRUMENTS

31, RIICO, Industrial Area, Jhotwara, Jaipur-302012, Rajasthan, India.

has been audited by ICV and found to be
in compliance with the requirements of the standard

ISO 9001:2015

(Quality Management Systems)

This certificate is valid for
the following scope:

Manufacturer, Marketing, Supply and After Sales Service of Various Types
of Scientific & Laboratory Instruments, Blood Bank Equipment, Hospital
Equipment and Sterilization Equipments.

Certificate No.	IN/ 55713744/ 2268
Certificate Issue Date	13/ 06/ 2024
1st Surveillance Due Date	13/ 05/ 2025
2nd Surveillance Due Date	13/ 05/ 2026
Date of Expiry	12/ 06/ 2027



Abhishek Singh

CEO
ICV ASSESSMENTS PVT. LTD.

25, First Floor, Prabhu Complex, Shiva Market, Pitampura New Delhi - 110034
+91 - 11-41548315, info@icvassessments.com, www.icvassessments.com

• Validity of this Certificate is subject to completion of surveillance audit on or before of due date. In case
Surveillance audit not allowed to be conducted this Certificate shall be suspended / withdrawn.
• This Certificate is intellectual Property of ICV and Certificate should be returned to ICV in case of non
compliance of certification procedure. Authenticity of this certificate can be verified at www.icvassessments.com



Certificate of Compliance

This is to certify that

AUTHENTIC INSTRUMENTS

31, RIICO INDUSTRIAL AREA, JHOTWARA, JAIPUR-302012,
RAJASTHAN, INDIA

Has been assessed by Optimum Certifications Inc. and found to be
in compliance with meeting the requirements of:

WHO-GMP Good Manufacturing Practice

For the following scope of activities:

**MANUFACTURE, MARKETING, SUPPLY AND AFTER SALES SERVICE OF ALL TYPES OF
SCIENTIFIC & LABORATORY INSTRUMENTS, BLOOD BANK EQUIPMENT, HOSPITAL
EQUIPMENT AND STERILIZATION EQUIPMENTS**

Date of Certification: 16th Aug. 2024
1st Surveillance Date: 15th July 2025

2nd Surveillance Date: 15th July 2026
Certificate Expiry Date: 15th Aug. 2027
(Subject to the company maintaining
its system to the required standard)

Certificate Number : WGMP-16082465

Validity of this certificate can be verified at www.ocicert.in

Authorised Signatory

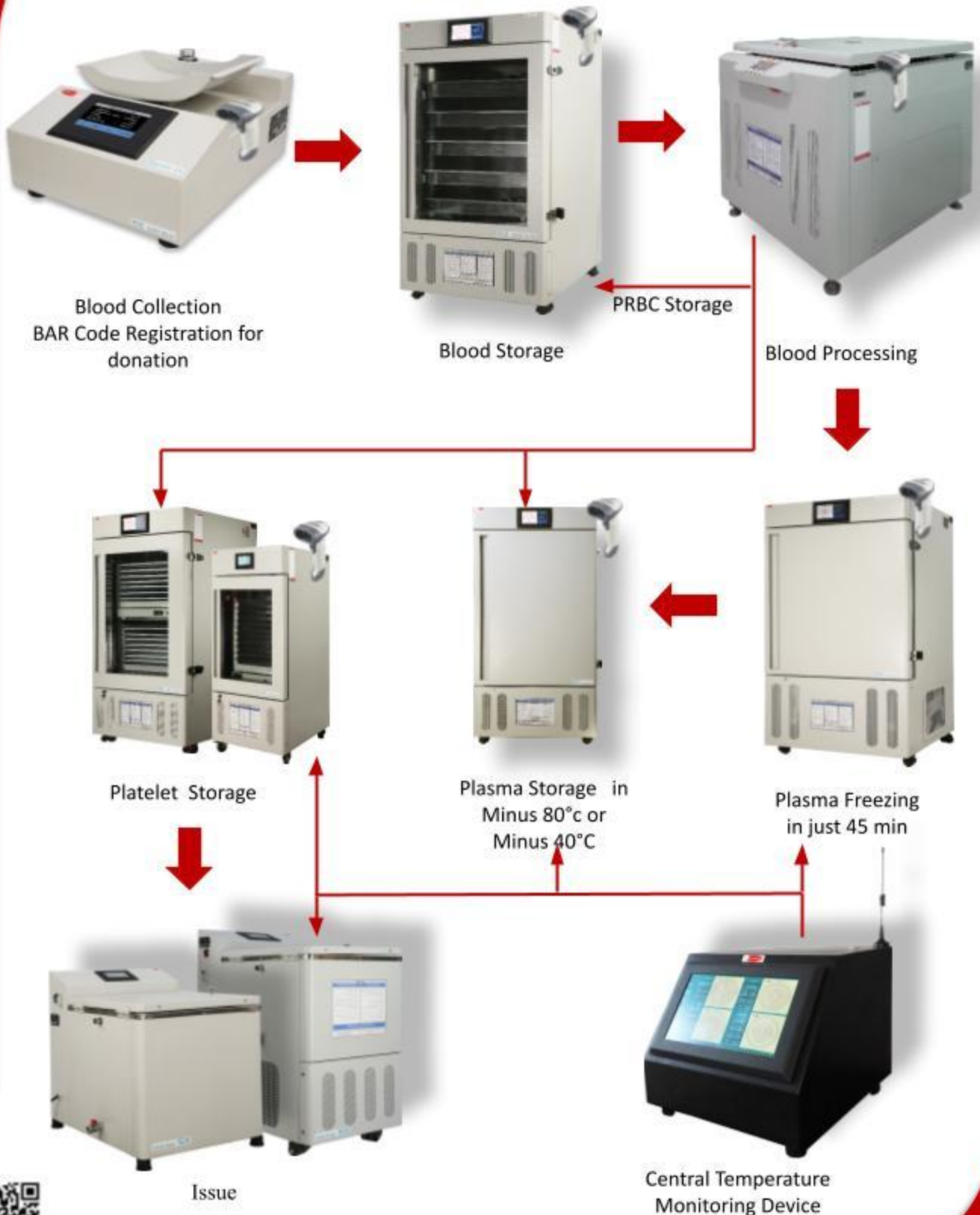


Validity of this Certificate is successful Annual Surveillance audits to be done. This certificate is the property of Optimum Certifications Inc. and shall be returned immediately upon request

Optimum Certifications Inc. is Accredited by UKSAF (www.uksaf.org.uk)

Suite 19, Regent Court, 70 West Regent Street, Glasgow, Scotland, G2 2QZ

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our Website

CDSCO MDR 2017 (MD-5) Overview under licence regime since june 2023

CDSCO MDR 2017 (MD-5) Overview: The Medical Device Rules (MDR) of 2017, implemented by the Central Drugs Standard Control Organization (CDSCO) in India, provide the regulatory framework for the manufacture, import, sale, and distribution of medical devices in the country. gazette notified on 2 june 2023 Starting from October 1, 2023, all categories fall under a licensing regime. Any manufacturer or importer intending to sell and distribute medical devices in India must possess a valid license (MD -5) from the Central Drugs Standard Control Organization (CDSCO).

<https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/Medical-Devices-Rules/>

CDSCO license For Class A & Class B Medical device

S. No.	License Number	License Holder Name	Device Name(Brand Name)-Intended Use	Approving Authority	Device Class
10852	MFG/MD/2023/001049	Authentic Instruments	Blood bank centrifuge (Blood Bank Centrifuge)(AUTHENTIC)-Intended to separate blood components of a suspension by application of centrifugal force.,Blood mixing and blood weighing devices (Blood collection monitor) (AUTHENTIC)-A blood mixing device is a device intended for medical purposes that is used to mix blood or blood components by agitation. Also intended to weigh blood or blood components as they are collected.,Blood mixing and blood weighing devices (Bucket equalizer)(AUTHENTIC)-Intended to weigh blood or blood component to balance in centrifuge bucket,Heat-sealing device (Tube Sealer)(AUTHENTIC)-A heat-sealing device is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.	Rajasthan	Class A
10853	MFG/MD/2023/001049	Authentic Instruments	Class-I biological safety cabinet(AUTHENTIC)-Provide a class I biosafety level (BSL) to the operator and the environment during the manipulation of microorganisms and other biological hazardous materials,Environmental chamber for storage of platelet concentrate (Platelet Agitator & Incubator)(AUTHENTIC)-A refrigerated environmental chamber for storage of platelet concentrate is a device used to hold platelet-rich plasma within a preselected temperature range,Blood storage refrigerator (Deep Freezer (-86°C))(AUTHENTIC)-These are devices intended for medical purposes that are used to preserve blood products by storing them at freezing temperatures.,Blood storage refrigerator (Deep Freezer (-20°C))(AUTHENTIC)-These are devices intended for medical purposes that are used to preserve blood products by storing them at freezing temperatures.,Blood storage refrigerator (Deep Freezer (-40°C))(AUTHENTIC)-Thsesse are devices intended for medical purposes that are used to preserve blood products by storing them freezing temperatures of upto -40°C,Blood storage refrigerator (Blood Bank Refrigerator)(AUTHENTIC)-These are devices are intended for medical purposes that are used to preserve blood by storing them at cold temperatures.,Blood storage refrigerator (Contact shock Freezer)(AUTHENTIC)-These are devices intended for medical purposes that are used to preserve blood products by storing them at freezing temperatures.	Rajasthan	Class B

Industry first why rely on



completely
indigenous industry

high end import
substitute

International and
national compliances

DQ-IQ-OQ-PQ-MQ

under licence regime as CDSCO as per MDR 2017 comply

self accessed communication after sale
service complaint log and update system

Blood Collection
Monitor

Contact Blast
Freezer
(up to 24 Bags)

Biological safety
Cabinet Class I (Laminar Air Flow)

Blood Bag Tube
Sealer

Blood Bank

Mother Milk
Bank

Clinical
Microbiology

Air steriliser

Customer care+91- 9352454200-400, support@authenticinstruments.com

Authentic Instrument Industries Limited



www.authenticinstruments.com

works,
31, industrial area jhotwara jaipur rajasthan- 302013

Customer care+91- 9352454200-400, support@authenticinstruments.com

Authentic Instrument Industries Limited

Corporate office,
G1,3/422, singhal enclave chitrakoot
scheme jaipur rajasthan- 302021

Branch office,
41, industrial estate jagatpur new IDCO
jagatpur (new) katak, odisha-754021