



# Certificate of Registration

*This is to certify that  
The Quality Management System of*

## FUSION BIOTECH

**Plot No. 6, Street No. 3, Mandir Mohalla, Samaipur,  
Delhi -110042**

*has been assessed and found to be in compliance  
with the requirements of the standard*

# ISO 9001:2015

**for the following scope :**

**Manufacture, Importer & Merchant of Blood Collection Tube, Micropipette  
Tips, Ria Vial, Disposable ESR Pipette, Urine Containers, Microscopic Glass  
Slide, Cover Slips, Multipurpose Vial, Centrifuge Tube, Tourniquet, Needle  
Destroyer, Micropipette, Centrifuge Machine, Incubator, Blood Roller  
Mixer, Blood Cell Counters, Water Bath, Hot Air Oven, VDRL Shaker,  
Calorimeter & Microscope, Laboratory Plasticware & Glassware Items.**

**CERTIFICATE NO. : 24ZAZQ1411Q**

**ISSUED DATE : 09/05/2024  
EXPIRY DATE : 08/05/2027**

**1ST SURVEILLANCE : 08/05/2025  
2ND SURVEILLANCE : 08/05/2026**



**Authorised Signatory**

**INTERNATIONAL QUALITY CERTIFICATION SERVICES UK LTD  
272, Bath Street, Glasgow, G2 4JR, U.K.**

This Certificate is intellectual Property of IQCS and can be maintained through surveillance and renewal audits.  
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The Registration is not a Product Quality Certificate.





# Certificate of Registration

*This is to certify that The Quality Management System of Medical Devices*

## FUSION BIOTECH

Plot No. 6, Street No. 3, Mandir Mohalla, Samaipur,  
Delhi -110042

*has been assessed and found to be in compliance with the requirements of the standard*

# ISO 13485:2016

for the following scope :

Manufacture, Importer & Merchant of Blood Collection Tube, Micropipette Tips, Ria Vial, Disposable ESR Pipette, Urine Containers, Microscopic Glass Slide, Cover Slips, Multipurpose Vial, Centrifuge Tube, Tourniquet, Needle Destroyer, Micropipette, Centrifuge Machine, Incubator, Blood Roller Mixer, Blood Cell Counters, Water Bath, Hot Air Oven, VDRL Shaker, Calorimeter & Microscope, Laboratory Plasticware & Glassware Items.

CERTIFICATE NO. : 24ZAZQ1412M

ISSUED DATE : 09/05/2024  
EXPIRY DATE : 08/05/2027

1ST SURVEILLANCE : 08/05/2025  
2ND SURVEILLANCE : 08/05/2026



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# Certificate of Compliance

*This is to certify that  
The Management System of*

**FUSION BIOTECH**

**Plot No. 6, Street No. 3, Mandir Mohalla, Samaipur,  
Delhi -110042**

*has been assessed and found to be in compliance  
with the requirements of the standard*

**GOOD MANUFACTURING PRACTICE**

**GMP**

**for the following scope :**

**Manufacture, Importer & Merchant of Blood Collection Tube, Micropipette  
Tips, Ria Vial, Disposable ESR Pipette, Urine Containers, Microscopic Glass  
Slide, Cover Slips, Multipurpose Vial, Centrifuge Tube, Tourniquet, Needle  
Destroyer, Micropipette, Centrifuge Machine, Incubator, Blood Roller  
Mixer, Blood Cell Counters, Water Bath, Hot Air Oven, VDRL Shaker,  
Calorimeter & Microscope, Laboratory Plasticware & Glassware Items.**

**CERTIFICATE NO. : 24ZAZQ1413G**

**ISSUED DATE : 09/05/2024  
EXPIRY DATE : 08/05/2027**

**1ST SURVEILLANCE : 08/05/2025  
2ND SURVEILLANCE : 08/05/2026**



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The Registration is not a Product Quality Certificate.





## Certificate of Compliance

This is to Certify that the following designated products :

### Annexure - I & II

This certificate is issued under the following conditions:

1. It applies only to the above referenced set of products mentioned above. The manufacturer is obligated to assure that all products of the respective model confirm to the type assessed by this certificate
2. The Certificate validity is conditioned by the positive result of the surveillance audits.
3. The Certificate remains valid until the manufacturing conditions, the quality systems or relevant legislation are changed but until the 08/05/2027
4. After Fulfilling the EU legislation requirements, the manufacturer shall affix to each product of the above referenced models, CE Marking according to the following example

**Manufactured By**  
**FUSION BIOTECH**

**Plot No. 6, Street No. 3, Mandir Mohalla, Samaipur,  
Delhi -110042**

*Conforms with the Applicable requirements of  
Pressure Equipment Directive (PED) 2014/68/EU*

CERTIFICATE No. : 24ZAZQ1414C

ISSUED DATE : 09/05/2024  
EXPIRY DATE : 08/05/2027

1ST SURVEILLANCE : 08/05/2025  
2ND SURVEILLANCE : 08/05/2026



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# Certificate of Compliance

**Manufactured By :**

**FUSION BIOTECH**

**Product Details**

## Products Name

### Annexure - A

- |                         |                            |
|-------------------------|----------------------------|
| Blood Collection Tube   | Ria Vial                   |
| Micropipette Tips       | Urine Containers           |
| Esr Disposable Pipette  | Micropipette               |
| Needle Destroyer        | Cover Slip                 |
| Microscopic Glass Slide | Centrifuge Tube            |
| Multipurpose Vial       | Micro Centrifuge Tube      |
| Hitachi Cup             | Alcohol Swab               |
| Test Tube Racks         | Lancet Device with Ejector |
| Swab Stick              | Micropipette Stand         |
| Glass Test Tubes        | Slide Staining Tray        |
| Blood Lancets           | Pipette Pump               |
| Patient ID Band         | Centrifuge Machine         |
| Medical Gloves          | Blood Roller Mixer         |
| Parafilm Roll           | Blood Cell Counters        |
| Tourniquet              | Slide Box                  |

**Annexure-I Certificate No:-24ZAZQ1414C**



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## *Certificate of Compliance*

**Manufactured By :**

**FUSION BIOTECH**

**Product Details**

### **Products Name**

#### **Annexure - B**

Calorimeter	Wintrobe Tube
Water Bath	Microtips Box
VDRL Shaker	Cuvettes
Incubator	ESR Tube Westerngreen
Lab. Oven	Cryo Vial
Microscope	Wash Bottle
B.P. Apparatus	Measuring Jug
Urine Strips Bio-chemistry	Swab Tube
Rapid Test Kits	Dressing Drums
Blood Glucose Strips	Cotton Roll
Digital Thermometers	Face Mask
Hot Water Bag	Petridish
Weighing Machine	Beakers
Fetal Doppler	Lab. Chemicals

**Annexure-II Certificate No:-24ZAZQ1414C**



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