



PT. MERSI BIOVAC PROINDO

USER REQUIREMENTS SPECIFICATION

BIOLOGICAL SAFETY CABINET URS-QC-2026-002 Rev 00

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activities at QC laboratory, including but not limited to raw material, IPC sample, drug product, microbiological agent, as well as microbiological and molecular reagent.

6. REQUIREMENT OF THE MACHINE

a. General requirement

BSC Class II Type A2 must be equipped with HEPA filter, have 70-30% circulation, have dedicated exhaust system to the room (ductless), and able to provide grade A cleanroom condition for QC testing. The instrument must be equipped with an inward airflow barrier draws room air into the front intake grille, preventing pathogens/harmful material from escaping into the laboratory.

b. Special requirement

N/A

7. INSTALLATION REQUIREMENTS

No.	Item/Machine Part		Requirement	
7.1	Utility Availability	Voltage	200-240 V 50/60 Hz	General electricity specification in Indonesia
		Exhaust system	Have dedicated exhaust system to the room	Ductless
7.2	Environment	Placement	Top floor	As per room layout
7.3		Temperature	20 – 24 °C	Grade C area
			16 – 25 °C	Grade CNC area
7.4		Relative Humidity	45 – 60%	Grade C area
			35 – 75%	Grade CNC area
7.5		Cleanness surrounding area	C cleanroom grade CNC grade	Refer to layout
7.6		Maximum weight	300 kg	N/A
7.7	7.8	Maximum external dimension (W x D x H)	150 x 100 x 180 cm	N/A
		Minimum external dimension (W x D x H)	120 x 60 x 60 cm	N/A

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8. OPERATIONAL REQUIREMENTS

a. Operational

Item	Description	Requirement	Remarks
8.a.1	Display	Touchscreen	Provide operational condition, including but not limited to: 1. Airflow 2. Alarm status 3. HEPA filter life
8.a.2	Material	- Easy to clean, VHP and alcohol disinfectant resistant. - Workzone material: SS 304 - Tempered glass, UV absorbing	Compatible with: 30-35% Hydrogen peroxide 70% ethanol or IPA
8.a.3	HEPA filter	H14	Filter efficiency NLT 99.995% at @ 0.3 um
8.a.4	Arm rest	Available	Optional
8.a.5	UV lamp	Available	N/A
8.a.6	Lighting	NLT 500 lux	Meet EN 12464-1 requirement
8.a.7	Internal electric socket	Available	Waterproof, suitable for clean area
8.a.8	Castor	Available	Can be locked
8.a.9	Datalogger	Preferably available	Data shall be transferred through USB port and non-editable

b. Power Failure/Recovery

No.	Requirements	Remarks
8.b.1	In case of power interruption, the instrument can be auto restart	N/A

c. Emergency Stop

No.	Requirements	Remarks
8.c.1	Emergency stop mechanism or button must be available	N/A

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d. Alarm and Warning

No.	Requirements	Remarks
8.d.1	Visual and audio alarm are available	N/A

e. Displayed Requirements

	Parameter	Format	Unit Measurement	Remarks
8.e.1	Date	XX.XX.XXXX	DD.MM.YYYY	N/A
8.e.2	Time	XX: XX	Hour : Minute	N/A
8.e.3	Air velocity	XX.XX	m/s	Two decimal
8.e.4	Filter time	XXX	Hour	N/A

9. PERFORMANCE REQUIREMENTS

Item	Description	Requirement	Remarks
9.1	Airflow circulation	70-30%	70% recirculated 30% exhausted to the room (ductless)
9.2	Air velocity	0,36 – 0,54 m/s	Meet grade A requirement (Annex 1 CPOB 2025, Annex 1 GMP 2022)
9.3	Workzone condition	Microbial limit (MAS, settle plate, contact plate, glove test): no growth Non-viable particle: 3520 (particle > 0.5 µm/m ³)	Meet grade A requirement (Annex 1 CPOB 2025, Annex 1 GMP 2022)

10. MAINTENANCE

A. Hardware and Software Maintenance Support

1. Easy to implement
2. The equipment will have a lifetime that is based on a warranty
3. The equipment shall be maintained in accordance with the timetable indicated by the Supplier. The following instructions should be given a minimum of supplier:
 - a. All sub-systems are provided (maintenance and operation of the equipment vendor manuals)
 - b. Supplier tell the address of the seller of spare parts and tools that can be calibrated locally and internally in Indonesia

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- c. Suppliers will meet two copies of the operation, installation, maintenance, troubleshooting and commissioning and soft copy manual
- d. Accessibility for operation and maintenance

B. Spare Parts and Accessories

1. Supplier will include all spare parts that's needed to be changed during warranty period and all accessories required for instrument to be operated as per list of requirements
2. Supplier will provide information regarding the duration required in ordering spare parts, the manufacturer's name and part number of spare parts.
3. Supplier can guarantee the availability of spare parts and accessories for at least 5 years.

11. ENVIRONMENT

Item	Description	Requirement
11.1	Layout	Based on internal layout
11.2	Physical Classification	a. Room explosion classification: NA b. Environmental classification: Class CNC, Class C clean room
11.3	Environmental Conditions	a. Environmental temperature: 20 - 24 °C (class C), 16 – 25 °C (CNC) b. Relative humidity: 45 - 60% (class C), 35 – 75% (CNC)

12. IMPACT ON HEALTH, QUALITY, SAFETY, AND ENVIRONMENTAL PROTECTION

- a. Safety notes contain important information on safety issues that may lead to personal injury, damage to the instrument, malfunctions and false results are available
- b. Safety and ergonomic aspect for operation handling should be taken care
- c. Easy maintenance and operation
- d. All control should be compacted in operation panel

13. SUPPLIER PRODUCED DOCUMENTS

The supplier of this equipment and system shall supply 2 sets of the following documents, in English.

- a. Operations and preventive maintenance manual from manufacturer
- b. Troubleshooting guidance
- c. Spare parts list including consumables list
- d. Emergency contact details
- e. IQ and OQ document
- f. Calibration documents: certificate, label, and report

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14. SCOPE OF SUPPLY AND COMMERCIAL DETAILS

1. Delivery
 - a. Delivery condition : QC Laboratory.
 - b. Delivery time : The supplier must state the delivery time in the quotation.
2. Support

No.	Requirements
1.	Start Up support
2.	Training for operation, troubleshoot, maintenance, and other things within user's scope
3.	Replacement parts available (normal lead time shall be informed)
4.	Telephone and E-mail
5.	Local technician is availability for troubleshooting and support service on working days

3. Warranty

Suppliers provide a guarantee for all equipment, components and installations for a minimum of 12 months starting from the receipt of certificates approved and issued by PT Mersi Biovac Proindo. The supplier must guarantee service within 24 hours of the local agent, or 72 hours if bringing in a specialist from the country of the machine supplier required.

15. QUALIFICATION DOCUMENTATION

The following documents must be made and executed at the time of commissioning, that is:

Documentation	Responsibility	Execution
Calibration	Supplier	Supplier + PT MERSI BIOVAC PROINDO
Installation Qualification (IQ)	Supplier	Supplier + PT MERSI BIOVAC PROINDO
Operational Qualification (OQ)	Supplier	Supplier + PT MERSI BIOVAC PROINDO

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