### SPECIFICATIE TEHNICA COMPLETATA

Modelul: Safemate EZ 1.2; DM Producator: Bioair, Tara: Italia

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către autoritatea ofertantă
Hotă cu flux laminar Clasa 2 B2	Hotă cu flux laminar Clasa 2 B2
Descriere Dulapuri biologice de siguranță care	Descriere Dulapuri biologice de siguranță care
cuprind clasa II, folosite pentru ventilare în	cuprind clasa II, folosite pentru ventilare în
laboratorul clinic. Exclude clasa I, clasa a III,	laboratorul clinic. Exclude clasa I, clasa a III,
Parametru Specificație	Parametru Specificație
Descriere Hotă microbiologică cu flux laminar	Descriere Hotă microbiologică cu flux laminar
vertical, clasa II tip B2	vertical, clasa II tip B2
Control controlat de microprocesor	Control controlat de microprocesor
sensor volumetric pentru monitorizarea	sensor volumetric pentru monitorizarea
fluxului de aer epuizat	fluxului de aer epuizat
control automat al volumului de flux prezentat	control automat al volumului de flux prezentat
Interior suprafața internă din oțel inoxidabil	Interior suprafața internă din oțel inoxidabil
antistatic	antistatic
Filtre HEPA sau ULPA	Filtre HEPA H14
Eficiența filtre ≥99.99 % pentru particule de	Eficiența filtre 99.999 % pentru particule de
0,3 microni	0,3 microni
	Efficiency >= 99.995% on 0.1-0.2 micron
	particles
Eficiența Prefiltru $\geq 85\%$ pentru particule de	Eficiența Prefiltru ≥ 85% pentru particule de
0,5 microni	0,5 microni
Lumina interioară lumină rece, integrată, cu	Lumina interioară lumină rece, integrată, cu
intensitatea de minim 800 lux	intensitatea de 750 lux
lampa UV pentru sterilizare, fixată în vitrina	lampa UV pentru sterilizare, fixată în peretele
frontală	din spate
Nivelul de zgomot nu mai mare de 65dB	Nivelul de zgomot 65dB
Flux aer mai mult de 0.4 m/s	Laminar Air Flow mean velocity
	$[EN12469](m/s): 0.35 \div 0.40$
	Inflow Air Barrier mean velocity
	$[EN12469](m/s): 0.56 \pm 10\%$
Afijaj digital	Afijaj digital
Alimentarea 220V, 50 Hz	Alimentarea 220V, 50 Hz
Alarme Acustică	Alarme Acustică
Vizuală	Vizuală
Capac de închidere a exhaustării	Capac de închidere a exhaustării - NU
Set de livrare Hota cu filtre	Set de livrare Hota cu filtre
Lampă de iluminare	Lampă de iluminare
lampă UV	lampă UV
suport pentru amplasarea hotei	suport pentru amplasarea hotei
Dimensiuni interioare Lungime - 130 ±10 cm	Dimensiuni interioare Lungime - 123 cm
Adîncime - 65±10 cm	Adîncime - 58 cm
Înalţime 65±10 cm	Înalțime 70 cm



### Safemate<sup>™</sup> EZ Series

### MICROBIOLOGICAL SAFETY CABINETS



- Fully EN12469 compliant
- State of the art microprocessor control system.
- Large digital display
- Air and aerosol-tight sliding sash, electrically operated by finger touch
- Alarms for low air flow and wrong front window position
- Sloped front and back wall for the most comfortable access
- Front access for filter maintenance and service
- C-shaped support stand with adjustable height
- Easy retrofit option kits
- HPV compatible for sterilization



Safemate EZ Cabinets are supplied in two different sizes (1.2mt and 1.8mt).

These last generation Microbiological Safety Cabinets Class II type A2, have been designed according to the most stringent safety standards (EN12469-2000).

The internal design, the air flow aerodynamics and monitoring, the built-in safety devices, and the very accurate manufacturing, guarantees the highest performances at the most stringent safety levels, as specified by EN12469 standard.

High intrinsic biological safety, combined with impressively competitive prices, gives the end user a state-of-the-art cabinet accessible to every budget, that only experienced European design and accurate quality manufacturing, can provide.

The EZ series sets a new standard for entry level cabinets combining a very attractive price with a full range of comfort options that were only available in more expensive cabinets.

### **Main specifications**

- Fully EN12469 compliant
- Microprocessor controlled motor blower, with volumetric sensor for exhausted air flow monitoring
- State of the art Microprocessor control system offering:
  - o Large screen monitor.
  - Automatic control of preset airflow volumes.
  - o Sliding sash window with smart control.
  - o Permanent monitoring of HEPA filters life span.
  - o Alarms. Multilevel alarms, with redundancy functions.
  - o Permanent display of working conditions.
  - High air flow stability both in case of transitional disturbances or to progressive filter clogging
  - o Continuous monitoring of front barrier air flow to guarantee operator safety
  - Low barrier alarm
  - Power failure alarm
- Volt-free contact for remote monitoring of exhaust fan.
- Automatic reset of initial conditions in case of power failure
- C-shaped support stand with adjustable height for easy one-man installation procedure

### **Mechanical and functional specifications**

- 5° Sloped front design to increase operational comfort. Sloped back side of the working chamber for the best down flow distribution
- Utilities inlets from the top of the cabinet.
- Stainless Steel internal surfaces with SB finishing (including spillage tray). Solid or perforated work surface (divided in sectors) and "V" shaped anti obstruction front grill.
- Electrically operated sliding multilayer safety glass window (max opening at 120°)
- Comfortable 200mm front opening
- Easy to install retrofit options through lateral sides.
- Exposed exhaust HEPA filter for easy visual integrity check.
- H14 class High Efficiency Particulate Air filters with 99.999% efficiency on .3micron particles (most penetrating particle diameter) (Efficiency >= 99.995% on 0.1-0.2 micron particles MPPS as per EN1822-1)
- Both exhaust and Main Filters are equipped with a micromesh membrane located downstream which acts as airspeed equalizer expansion plenum, as well as a clear indicator of filter damages.
- Filter change and maintenance from the front of the cabinet.
- Exhaust transitions easily installable.
- Key operated. The key can be removed when the unit is in SAFE mode, to avoid unwanted operation. In case of power failure, the cabinet is re-set to original working conditions.



- Self-calibration cycle performed when cabinet is switched on.
- Visual display of SAFE conditions. Pre-warning before actual alarm condition is reached (visual and acoustic alarms)
- Soft touch control with keys for standard service utilities. Interconnected UV and fluorescent lights.
- Microprocessor equipped with analogical watch dog.

#### **Default utilities**

- UV lamp on back wall. Controlled by control panel with timer for delayed start and cycle duration (max 1h)
- Two power sockets (Shucko/Europlug standard). Other socket standards are available as options
- Glare free fluorescent lights

### **Optional utilities**

- Compressed air/vacuum tap. Installs on the right wall.
- Combustible gas tap with solenoid safety valve. Installs on the right wall.
- HPV adapter kit (inlet camlock on left wall and outlet camlock connector on transition adapter)
- Additional sockets and sockets standards (max power overall 3Amperes)
- Passive and active transition adapters or thimble for ducting

### **Technical Features Safemate EZ Series**

DESCRIPTION	SIZE 1.2	SIZE 1.8	
1.1 POWER SUPPLY			
Mains supply voltage:	220-240 V	∨ 50/60 Hz	
Required power line (W): (700 W service socket included)	1200	1750	
Absorbed power (W): (fan and light on only)	375	650	
Main fuses rating:	F10A H, 250 V ( <b>Material:</b> steatite – <b>Size:</b> 5x20 - <b>I<sup>2</sup>t:</b> 121)		
Electrical insulating/protection class [IEC 61140]:	I		
IP protection degree:	Ordinary equip	oment (IP10B)	
1.2 REFERENCE STANDARDS			
SAFETY:	IEC 61010-1:2010 / EN 61010-1:2010		
EMC:	IEC 61326-1:2012 / EN 61326-1:2013		
MICROBIOLOGICAL SAFETY:	EN 12469:2000		
1.3 DECLARATIONS AND APPROVALS			
Mark of conformity:	CE		
1.4 USE ENVIRONMENTAL CONDITIONS			
Use:	indo	or	
Altitude (m):	up to 2000		
Temperature (°C):	from 10 to 35		
Maximum relative humidity (%):	80 for temperatures up to 31 °C, decreasing linearly to 50 at 40 °C		
Max MAINS supply voltage fluctuations (%):	up to ±10		
TRANSIENT OVERVOLTAGE CATEGORY:	II		



POLLUTION DEGREE: 2				
1.5	TRANSPORT AND STORAGE CONDITI			
Ambie	nt temperature (°C):	from -5 to 45		
Relativ	ve humidity (%):	up to	90	
Atmos	pheric pressure (mbar):	from 800	to 1060	
1.6	WEIGHT AND DIMENSIONS			
Weight	t (kg):	260	360	
	l dimensions L x D x H (mm): ut support stand)	1380 x 780 x 1450	1990 x 780 x 1450	
BioAir support stand authorized heights (mm):		690, 730, 770, 810		
Front a	aperture dimensions L x H (mm):	1165 x 195 1775 x 195		
Workir	ng space dimensions L x D x H (mm):	1230 x 580 x 700	1840 x 580 x 700	
Safe w	orking area dimensions L x D (mm):	1030 x 350	1640 x 350	
1.7	MATERIALS			
Main s	tructure: cold rolled steel, epoxy powder coated		oxy powder coated	
Walls inner surface of the working area: stainless steel AISI 304 - SB finishing		304 - SB finishing		
Workir	ng surface:	stainless steel AISI	304 - SB finishing	
Front v	window:	laminated s	afety glass	
1.8	PERFORMANCES			
Intend	led life of the equipment (years):	10	)	
	ar Air Flow mean velocity [EN ](m/s):	0,35 ÷ 0,40		
	Air Barrier mean velocity [EN ](m/s):	0,56 ±10%		
Exhaus	st Air flow rate (m³/h):	450 ±10%	600 ±10%	
Exhaus	st Air flow ratio (%):	30 ±1	10%	
	Aperture Protection Factor [EN 12469]: tion efficiency at front aperture)	≥1,0 x 10 <sup>5</sup>		
Workir 14644	ng space air cleanliness class [EN -1]:	ISO 3		
Illumin	nance [EN 12469] (lux):	>750		
Sound	level [EN ISO 3744] (dB[A]):	<6	5	
Vibrati	on [EN 12469] (mm RMS):	<0,0	005	
	crease inside cabinet in temperature he ambient [EN 12469] (°C):	<5		
Leaktion 12469	ghtness index of the cabinet housing [EN ]:	LI-C		
Cleana	ability index [EN 12469]:	CI-B		
Steriliz	zability index [EN 12469]:	SI-B		
1.9				
LAF filter dimensions L x D x H (mm):		1219 x 610 x 68	1829 x 610 x 68	
	Iter dimensions L x D x H (mm):			
	efficiency class [EN 1822-1]:			
	Iters global MPPS efficiency [EN 1822-1](%): 99,995			
MPPS diameter [EN1822-1](μm):		0,1 ÷		



1.10 OTHER FEATURES			
Out VFC [voltage free contact] (Vmax; A)	24; 2		
Electrical service sockets total max current (A):	3		
Fluorescent lamps power (W):	2x 30	2x 58	
Type of fluorescent lamp:	tubular T8		
Lamp light colour	84	0	
Lamp colour temperature (K):	4000		
Fluorescent lamp average life at 90% yield (h):	12000		
UV-C lamp power (W):	1x 30	1x 40	
Type of UV-C lamp:	tubular T8	tubular T10	
UV-C spectral peak (nm):	253,7		
UV-C lamp average life (h):	8000		
Surface power density of UV-C lamp at 1 m (µW/cm2):	117	151	
Window glass UV-C radiations retention (%):	≥ 98		
Impact maximum energy sustainable by the glass front window [EN 61010-1, clause 8.2.2] (J):	4		
1.11 OPTIONAL ACCESSORIES FEATURES			
Combustible gas fixture max pressure (mbar):	20		
Inert fluids/vacuum fixture max pressure (bar):	6		

These Microbiological Safety Cabinets, are manufactured according to EN12469:2000







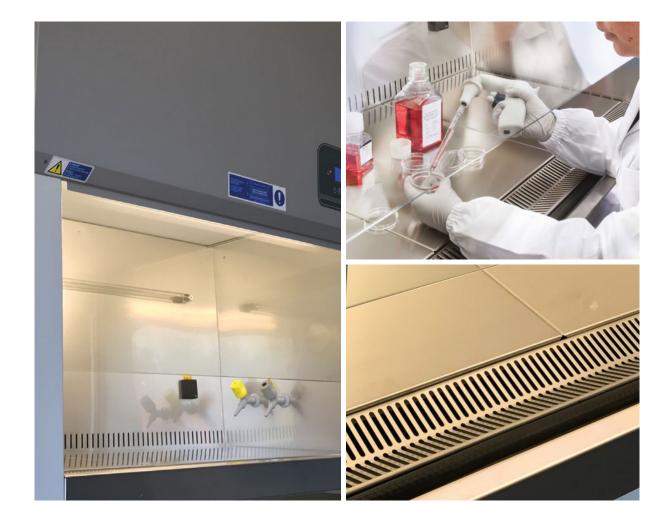
SAFEMATE EZ BIOAIR

STAY SAFE THE EZ WAY

### STAY SAFE THE EZ WAY

Including premium features in an entry level priced cabinet, the new Class II (type A2) Microbiological Safety Cabinets SafeMate EZ series allow everybody to stay safe in an easy way. The "V"-shaped antiobstruction grill allows working without worrying about armrests, while the self positioning electrically operated front sash makes sure that the front aperture is always at the right size for comfort and safety. **Your Safety is our Commitment.** 

No compromise for Operator, Product and Environment. Protection guaranteed as required by EN12469:2000 standard.



SAFEMATE EZ BIOAIR FEATURE RICH

### **FEATURE RICH!**

**Electrical front sash:** the front glass is operated using the switches on the main control panel allowing effortless opening and closing of the working area.

**V-shaped front grill:** forget about armrests limiting your working position: SafeMate's Vshaped front grill ensures the front barrier is always at its best.

**Customizable utilities:** want more space in the working area? Do not take the optional taps if. Changed your mind and want the taps? Just buy the option and they will be installed in your cabinet even after sales!

**Fully VHP compliant:** with the optional VHP connector kit you can easily use any Hydrogen

Peroxide vapour generation system to fully sterilize your cabinet.



### **SAFEMATE EZ**

CLASS II MICROBIOLOGICAL SAFETY CABINET





An elegantly crafted standard control panel and display, for your convenience



Sloped front for the most comfortable access



UV Lamp on back wall (standard)



Air/Aerosol tight electrical sliding sash with exclusive "yzy" movement





### **Italian Quality**

Our cabinet are completely made in Italy using components of italian or european origins! We use only the best for our cabinets!





Silent operation: <49dB(A)

Electrically operated front sash

Gas & Vacuum taps (optional, retrofittable)



Anti obstruction "V" shaped front grille

Height adjustable support stand

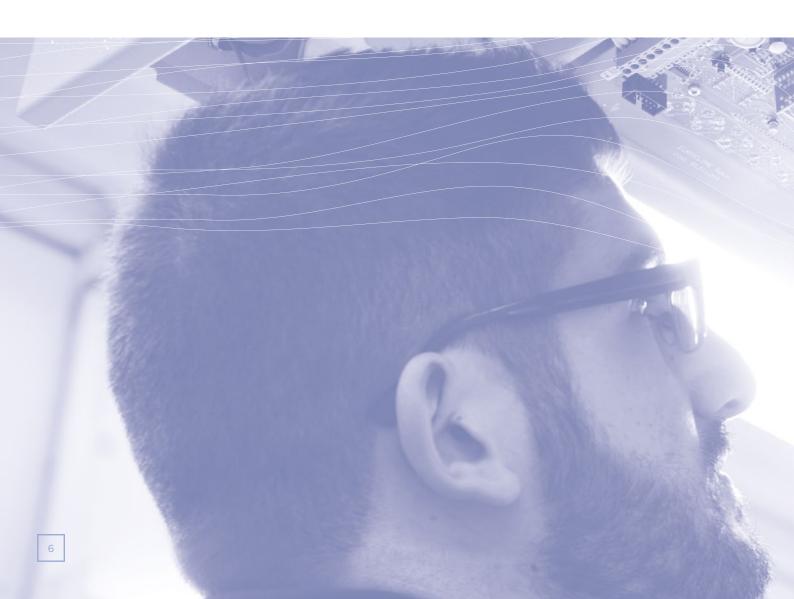
### Choose your color!



### **MAIN SPECIFICATIONS:**

- State of the art AC motorblower enhances energy efficiency, reducing operating costs.
- ✓ Fully compliant Class II microbiological safety cabinet according to EN 12469 safety standard
- ✓ Air and aerosol tight electrical sliding sash
- ✓ UV light on back wall
- √ 5° Sloping front aperture to maximise comfort.
- √ V-Shaped anti-obstruction front grill
- $\checkmark$  Optional utilities for gas and vacuum, installable in-field
- ✓ Real Time reporting of air speeds (inflow & downflow)
- ✓ Fully stainless steel working chamber and surface.





### STANDARD UTILITIES

STANDARD ELECTRICAL EQUIPMENT		
Automatic electronic airflow velocity control PCB	$\checkmark$	
Motorblower (fan)	$\checkmark$	
Inverter	$\checkmark$	
Fluorescent lamps	$\checkmark$	
Sliding window electric motor	$\checkmark$	
Combustible gas solenoid valve.	V	_
STANDARD UTILITIES		
Tap for combustible gas line	Optional	
Tap for inert fluids/vacuum line	Optional	
Auxiliary electrical service socket	$\checkmark$	
2nd auxiliary electrical service socket	$\checkmark$	
UVC lamp socket	$\checkmark$	
Voltage-free contact (VFC) outlet	$\checkmark$	



### **OPTIONS & ACCESSORIES**

CODE	DESCRIPTION	NOTES	SIZE 0.9	SIZE 1.2
AC10000	CHEST DRAWER	2 drawers - with castors	√	√
AS1L410	SUPPORT STAND 1.2	h= 730 - 890 mm	$\checkmark$	
AS1L610	SUPPORT STAND 1.8			√
AZ1L010	CASTORS KIT	With retractable foot	$\checkmark$	$\checkmark$
AP1K604	IV bar for 1.2	(includes 10 hooks)	$\checkmark$	
AP1K606	IV bar for 1.8			$\checkmark$
AZ1H613	ARMRESTS		$\checkmark$	$\checkmark$
DUCTING AND A	ADDITIONAL FILTERS OPTIONS			
AZ1H124	Active extraction kit		$\checkmark$	
AZ1H154	Additional charcoal filter adapter		$\checkmark$	
CP62000	Additional charcoal filter	Requires AZ1H126 and AZ1H156	$\checkmark$	
AZ1H126	Active extraction kit			√
AZ1H156	Additional charcoal filter adapter			$\checkmark$
CP66000	Additional charcoal filter	Requires AZ1H124 and AZ1H154		√
AZ1H2O4	Passive transition adapter kit	Requires remote blower for	$\checkmark$	
AZ1H206	Passive transition adapter kit	extraction		$\checkmark$
AZ1H304	Extraction open hood ("thimble")	Requires remote blower for	$\checkmark$	
AZ1H306	Extraction open hood ("thimble")	extraction		$\checkmark$

### **TECHNICAL DATA**

DESCRIPTION	SIZE 1.2	SIZE 1.8		
Part No. (cabinet)	LDK400N	LDK600N		
Part No. (Solid Work Surface)	AZ9K040	AZ9K060		
Part No. (Perforated Work Surface)	AZ9K041	AZ9K061		
SPECIFICATIONS				
Reference Standards:	IEC 61010-1:2010 / EN 6101 IEC 61326-1:2012 / EN 6123 EN 12469:2000			
Electrical insulating/protection class [IEC 61140]:	I	l		
Mains supply voltage:	220-240 V	~ 50/60 Hz		
Required power line (W): (700 W service socket included)	1200	1750		
Absorbed power (W): (*) (fan and light on only)	465	774		
Window glass UVC radiations retention (%):	9	8		
Combustible gas fixture max pressure (mbar):	20	0		
Inert fluids/vacuum fixture max pressure (bar):	2	1		
Electrical service socket max current (A):	3	3		
WEIGHT AND SIZE				
Net Weight (kg):	256	360		
Overall size L x D x H (mm): (without support stand)	1380 x 795 x 1450	1990 x 795 x 1450		
Front aperture size L x H (mm):	1230 x 200	1840 x 200		
Working space size L x D x H (mm):	1230 x 600 x 700	1840 x 600 x 700		
MATERIALS				
Main structure:	cold rolled steel, stove enamel of	coated RAL 7035 + ABS plastic		
Working space surface:	stainless steel AISI	304 - SB finishing		
Front and side walls windows:	laminated s	safety glass		
PERFORMANCES				
Laminar Air Flow mean velocity [EN 12469](m/s):	0,33 ÷	- 0,40		
Inflow Air Barrier mean velocity [EN 12469](m/s):	0,53	±10%		
Exhaust Air flow rate (m3/h):	480 ±10%	600 ±10%		
Exhaust Air flow ratio (%):	30	±10		
Apf - Aperture Protection Factor [EN 12469]: (Retention efficiency at front aperture)	≥1,0 >	x 105		
Working space air cleanliness class [EN 14644-1]:	ISC	D 5		
Illuminance [EN 12469] (lux):	>850	<54		
Sound level [EN ISO 3744] (dB[A]): (**)	<56	<60		
Vibration [EN 12469] (mm RMS):	<0,0	005		
Max increase inside cabinet in temperature from the ambient [EN 12469] (°C):	<	5		
FILTERS				
Filters efficiency class [EN 1822-1]:	H14	(***)		
Filters global MPPS efficiency [EN 1822-1](%):	99,9	995		
MPPS diameter [EN1822-1](μm):	0,1 ÷	- 0,3		

<sup>\*</sup> Motorblower on, lights on (flow 0.28m/s, LED lights)
\*\* Measured in operating conditions. Actual values at customer site may be different due to room structure
\*\*\* Efficiency higher than ULPA (Class F) as per IESP-RP-CC001

## OVER 40 YEARS OF EXPERIENCE

BioAir has been manufacturing Biohazard and Laminar Air Flow cabinets since the early '70s, when the Gelaire® brand became the "gold standard" for airborne contamination control in laboratories all over the world.

A family of Recirculating Fume Hoods, based on the adsorption of toxic vapors by charcoal filters, was successfully introduced a few years later, thus positioning the Company as the only one seriously focused on the protection of its operators, in line with its inspiring motto "Your safety is our commitment".

This unique know-how and insistence on quality were continually developed, and 25 years on, under the name of BioAir®, the entire range was completely re-designed to meet the changing requirements of laboratory staff and increasingly stringent regulations.

At the top of the range are the Biohazard Cabinets (or Microbiological Safety Cabinets - MSC), the sum of the Company's know-how, certified to European standards (EN12469:2000) and also complying with Australian regulations. In other words, they are designed to provide technicians with the maximum level of safety when used according to GLP/GMP standards in their respective environments.

Today, in a facility occupying over 2,800 square meters, BioAir

manufactures a full range of microbiological safety cabinets, laminar flow cabinets and fume cupboards, with over 15 models, many of which available in different sizes. Customized models and cabinets designed for specific applications can be produced by our team of skilled engineers and operators.

Decades of experience in sales and support for cell biologists have enabled BioAir to give the market an extremely innovative CO<sub>2</sub> Incubator, the Safegrow® PRO, the fruit of deep knowledge of the optimum conditions required for critical tissue culture methods and input from scientists engaged in growing cells in vitro.

The core business of the recently established BioAir® Industrial Team is the design, manufacturing and validation of customized equipment for the protection of the operator and of the product in pharmaceutical and healthcare production facilities.

This dedicated team will leverage the long experience and production capability acquired in laboratory LAF applications to offer complex equipment ranging from **dispensing/sampling Downflow Booths** and **Clean Rooms** to **RABS** and **Isolators** for Regenerative Medicine and Advanced Cell Therapy.

## PLUS BIOAIR

### **MADE IN ITALY**

Our products are designed and produced in Italy, drawing on the long tradition and internationally recognized high quality of Italian manufacturing, to bring you the best equipment for your safety.

### TRADITION AND EXPERIENCE

All our Microbiological
Safety Cabinets were
designed with your safety
in mind and that's a task
where even the smallest
details count. Our team
stems directly from the
company that launched
the market for MSCs in
Europe, so we put a lot
of history and experience
into all our products, as
well as care over those
often-overlooked details
that improve your safety.

### WE CARE FOR YOU

Thanks to our network of highly trained dealers and distributors, our complete portfolio and long experience in the field, we will always be able to help you find the right product for your needs, no matter how unique they are. And our commitment doesn't stop there: our Service network will make sure your equipment always performs at its best.



BioAir S.p.A. Via Figino, 20/22 20016 Pero (MI) Italy T +39 0382 66721 M info@bioair.it

www.bioair.it



## Dasa-Rägister

### IQ-0720-07

Certificato n.

### 2020-07-13

Data di prima emissione First issue date

### 2023-06-20

Data di ultima emissione Last issue date

### 2026-07-12

Data di scadenza Expiry date

C.E.O.

Dasa-Rägister S.p.A. Italy – 00071 Pomezia – Roma Via dei Castelli Romani, 22 Tel. +39-0691622002 Fax +39-069107126 www.dasa-raegister.com



SGQ Nº 052

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC Signatory of EA, IAF and ILAC Mutual Recognition Agreements

### Dasa-Rägister S.p.A.

certifica che il sistema di gestione per la qualità di certifies that the quality management system of

## Bioair S.p.A.

Italia - 27010 - Siziano (PV) - Via Lombardia, 12

E' stato verificato e trovato conforme ai requisiti dello standard Has been assessed and found in compliance with the standard requirements

## **UNI EN ISO 9001:2015**

Per le seguenti attività aventi come oggetto

Progettazione, sviluppo, produzione, collaudo, assistenza tecnica e commercializzazione di cabine, isolatori, incubatori e strumenti per il controllo della contaminazione e per il contenimento biologico e chimico. Assistenza tecnica su strumenti e apparecchiature per le biotecnologie

For the following activities having as object

Design, development, production, testing, technical support and trade of cabins, isolators, incubators and instruments for the contamination control and biological and chemical containment. Technical support on biotechnology products and equipment

Settore/i - Sector/s 19 29

Informazioni puntuali e aggiornate circa lo stato della presente Certificazione sono disponibili all'indirizzo www.dasa-raegister.com

Punctual and updated information regarding this Certification is available at www.dasa-raegister.com

Riferirsi alla documentazione del Sistema di Gestione Qualità dell'Organizzazione per i dettagli delle singole esclusioni ai requisiti della Norma ISO 9001:2015.

La validità del presente Certificato è subordinata al rispetto delle prescrizioni del Regolamento di Certificazione Dasa-Rägister, dei requisiti della Norma ISO 9001:2015, ad un programma di sorveglianza annuale e ad un riesame ogni tre anni

Refer to the Documents of the Quality Management System of the Organizaztion for details regarding the esclusions to ISO 9001:2015 Standard requirements.

The validity of this Certificate is subordinated by a full respect of that prescribed in Dasa-Rägister's Certification Regulation, of ISO 9001:2015 Standard requirements, to an annual surveillance programme and to a three yearly reassessment.



# Certificate

on the inspection of a product manufacturing facility applied for TÜV NORD CERT approval marks

BioAir S.p.A Via Lombardia 12 27010 Siziano (PV) Italy

Manufacturing facility:

BioAir S.p.A Via Lombardia 12 27010 Siziano (PV)

Italy

Products:

Microbiological safety cabinets

Date of inspection:

19.-20.04.2023

Inspection summary:

The applicant was able to demonstrate that the manufacturing facility is technically equipped and managed in such a way that uniform production is guaranteed for the listed product(s).

Certificate Registration No. 44 786 137265 Audit Report No. 3534 4471

File-No. 8003056471

Validity

Valid from 2023-04-19

Valid until 2024-04-18

Essen 2023-04-25

TÜV NORD CERT GmbH, Certification Body Consumer Products

TÜV NORD CERT GmbH Am TÜV 1 45307 Essen www.tuev-nord-cert.com prodcert@tuev-nord.de

TÜV®



### DICHIARAZIONE DI CONFORMITÀ CE/UE

EC/EU DECLARATION OF CONFORMITY

IL FABBRICANTE: THE MANUFACTURER:

BioAir S.p.A.

Via Lombardia, 12 27010 Siziano (PV) - Italia

DICHIARA CHE I SEGUENTI PRODOTTI: HEREWITH DECLARES THAT THE FOLLOWING PRODUCTS:

MODELLO - MODEL

CODICE - CODE

S@feMate EZ 1.2 S@feMate EZ 1.8 LDK400N LDK600N

DESCRIZIONE: CABINE DI SICUREZZA MICROBIOLOGICHE DI CLASSE II

CLASS II MICROBIOLOGICAL SAFETY CABINETS DESCRIPTION:

SONO CONFORMI ALLE SEGUENTI DIRETTIVE FUROPEE:

ARE IN CONFORMITY WITH THE FOLLOWING EUROPEAN DIRECTIVES:

2006/42/CE Direttiva Macchine 2006/42/EC Machinery Directive

2014/30/UE Direttiva Compatibilità Elettromagnetica 2014/30/EU Electromagnetic Compatibility Directive

E CHE SONO STATE APPLICATE LE SEGUENTI NORME EUROPEE ARMONIZZATE: AND THAT THE FOLLOWING HARMONIZED EUROPEAN STANDARDS HAVE BEEN APPLIED:

EN 61010-1:2010 ■ Prescrizioni di sicurezza per apparecchi elettrici di misura, controllo e per utilizzo

+A1:2019

in laboratorio. Parte 1: Prescrizioni generali.

IEC 61010-1:2010

Safety requirements for electrical equipment for measurement, control and

+A1:2016 | laboratory use. Part 1: General requirements.

IEC 61326-1:2012

EN 61326-1:2013 | Apparecchi elettrici di misura, controllo e laboratorio - Prescrizioni di compatibilità elettromagnetica. Parte 1: Prescrizioni generali.

Electrical equipment for measurement, control and laboratory use - EMC requirements. Part 1: General requirements.

EN 12469:2000

Biotecnologie - Criteri di prestazione per cabine di sicurezza microbiologiche. Biotechnology - Performance criteria for microbiological safety cabinets.

Persona autorizzata a costituire il fascicolo tecnico: Person authorized to compile the technical file:

Ing. Davide Desidera

(Direttore operativo) (Operation manager)

Indirizzo: c/o

Address: at

BioAir S.p.A. via Lombardia, 12 - 27010 Siziano (PV) Italy

Luogo, data Place, date

Siziano, 31/08/2021

Ing. Ermanno Baj Amministratore delegato / C.E.O.

CE00016R02

1/1