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*	***LDK400N***
S@feMate EZ *1.8*	***LDK600N***

DESCRIZIONE: CABINE DI SICUREZZA MICROBIOLOGICHE DI CLASSE II
DESCRIPTION: CLASS II MICROBIOLOGICAL SAFETY CABINETS

SONO CONFORMI ALLE SEGUENTI DIRETTIVE EUROPEE:
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 +A1:2019 IEC 61010-1:2010 +A1:2016	Prescrizioni di sicurezza per apparecchi elettrici di misura, controllo e per utilizzo in laboratorio. Parte 1: Prescrizioni generali. *Safety requirements for electrical equipment for measurement, control and laboratory use. Part 1: General requirements.*
EN 61326-1:2013 IEC 61326-1:2012	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

Digitally signed by Ceaicovschi Tudor
Date: 2023.07.10 17:52:47 EEST
Reason: MoldSign Signature
Location: Moldova

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

CE00016R02

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EN ISO 9001

Dasa-Rägister

IQ-0720-07

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Certificate n.

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ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 052A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreements

CERTIFICATE

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 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. Sanificazione e disinfezione di locali, unità di trattamento aria e ambienti confinati

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. Sanitization and disinfection of premises, air treatment units and confined spaces

Settore/i - Sector/s **19 - 29 - 35**

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 re-assessment.

S@femate™ 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

S@femate 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:
    - Large screen monitor.
    - Automatic control of preset airflow volumes.
    - Sliding sash window with smart control.
    - Permanent monitoring of HEPA filters life span.
    - Alarms. Multilevel alarms, with redundancy functions.
    - Permanent display of working conditions.
    - High air flow stability both in case of transitional disturbances or to progressive filter clogging
    - 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 *oneman 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 (cabinet carcass EN12298 tested and certified for air tightness)
- 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, in order 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 conditions are 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

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 S@femate EZ Series

Model	**1.2**	**1.8**
Part No.	LDK4000 (solid w/s) LDK4001 (perforated w/s)	LDK6000 (solid w/s) LDK6001 (perforated w/s)
Overall dimensions (lxwxh) mm	1380x795x1450	1990x795x1450
Useful dimensions (lxwxh) mm	1230x600x700	1840x600x700
Weight kg	256	360
Front barrier air speed	≥ 0.5mt/sec	
Aperture protection Factor (Apf)	≥ 1.5×10^5	
Front aperture mm	200	
Cleanability Index	CC grade	
Light intensity on work surface	> 900 lux	
Work surface displacement (vibration)	<0.005mm RMS between 20Hz and 20,000Hz	
Power supply	AC 230V, 50/60Hz	

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

SAFEMATE EZ

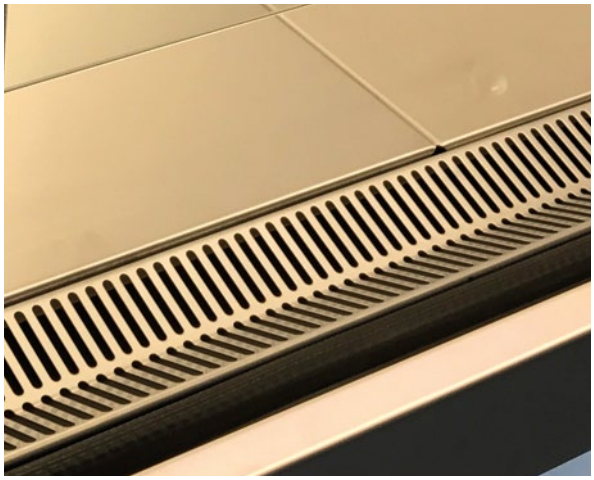
CLASS II MICROBIOLOGICAL SAFETY CABINET

BIOAIR®

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.



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

made in ITALY

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
- 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	√
Motorblower (fan)	√
Inverter	√
Fluorescent lamps	√
Sliding window electric motor	√
Combustible gas solenoid valve.	√
STANDARD UTILITIES	
Tap for combustible gas line	Optional
Tap for inert fluids/vacuum line	Optional
Auxiliary electrical service socket	√
2nd auxiliary electrical service socket	√
UVC lamp socket	√
Voltage-free contact (VFC) outlet	√

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	√	
AS1L610	SUPPORT STAND 1.8			√
AZ1L010	CASTORS KIT	With retractable foot	√	√
AP1K604	IV bar for 1.2	(includes 10 hooks)	√	
AP1K606	IV bar for 1.8			√
AZ1H613	ARMRESTS		√	√
DUCTING AND ADDITIONAL FILTERS OPTIONS				
AZ1H124	Active extraction kit		√	
AZ1H154	Additional charcoal filter adapter		√	
CP62000	Additional charcoal filter	Requires AZ1H126 and AZ1H156	√	
AZ1H126	Active extraction kit			√
AZ1H156	Additional charcoal filter adapter			√
CP66000	Additional charcoal filter	Requires AZ1H124 and AZ1H154		√
AZ1H204	Passive transition adapter kit	Requires remote blower for extraction	√	
AZ1H206	Passive transition adapter kit			√
AZ1H304	Extraction open hood ("thimble")	Requires remote blower for extraction	√	
AZ1H306	Extraction open hood ("thimble")			√

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 61010-1:2010 IEC 61326-1:2012 / EN 61236-1:2013 EN 12469:2000	
Electrical insulating/protection class [IEC 61140]:	I	
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 (%):	98	
Combustible gas fixture max pressure (mbar):	20	
Inert fluids/vacuum fixture max pressure (bar):	4	
Electrical service socket max current (A):	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 coated RAL 7035 + ABS plastic	
Working space surface:	stainless steel AISI 304 - SB finishing	
Front and side walls windows:	laminated 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]:	ISO 5	
Illuminance [EN 12469] (lux):	>850	<54
Sound level [EN ISO 3744] (dB[A]): (**)	<56	<60
Vibration [EN 12469] (mm RMS):	<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](%):	99,995	
MPPS diameter [EN1822-1](µm):	0,1 ÷ 0,3	

* 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_2 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.

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