

Lot 7, Hotă cu flux laminar**Safemate EZ 1.2, Bioair(Euroclone), Italia**

Parametri solicitati	Parametri oferiti
Descriere Dulap biologic cu flux laminar, pentru manipularea culturilor celulare într-un mediu aseptice.	Descriere Dulap biologic cu flux laminar, pentru manipularea culturilor celulare într-un mediu aseptice.
Dimensiuni interne (zona de lucru): $\geq 1190 \times 630 \times 630$ mm	Dimensiuni interne (zona de lucru): 1230 x 580 x 700 mm
Parametru Specificație	Parametru Specificație
Control controlat de microprocesor sensor volumetric pentru monitorizarea fluxului de aer epuizat control automat al volumului de flux prezentat	Control controlat de microprocesor sensor volumetric pentru monitorizarea fluxului de aer epuizat control automat al volumului de flux prezentat
Interior suprafața internă din oțel inoxidabil antistatic	Interior suprafața internă din oțel inoxidabil antistatic
Filtre HEPA sau ULPA Prefiltru	Filtre HEPA Prefiltru
Eficiența de minim 85 %, pentru particule de minim 0.5 microni, clasa G4	Eficiența de 99,995%, pentru particule de minim 0.3 microni, clasa H 14 H14 class High Efficiency Particulate Air filters with 99.999% efficiency on 0.3micron particles (most penetrating particle diameter) (Efficiency $\geq 99.995\%$ on 0.1-0.2 micron particles MPPS as per EN1822-1)
Lumina interioară lumină rece, integrată, cu intensitatea de minim 800 lux	Lumina interioară lumină rece, integrată, cu intensitatea de > 750 lux
lampa UV pentru sterilizare, fixată în vitrina frontală	lampa UV pentru sterilizare, fixată în vitrina frontală
Nivelul de zgomot nu mai mare de 68dB	Nivelul de zgomot 65 dB
Flux aer mai mult de 0.4 m/s	Flux aer $0,56 \pm 10\%$
Factorul de protecție (Apf) $1.0 \cdot 10^5$	Factorul de protecție (Apf) $1.0 \cdot 10^5$
Afijaj digital	Afijaj digital
Alimentarea 220V, 50 Hz Alarmer	Alimentarea 220V, 50 Hz Alarmer
Acustică Vizuală	Acustică Vizuală
Capac de închidere a exhaustării -optional	Capac de închidere a exhaustării -nu
Set de livrare Hota cu filtre Lampă de iluminare lampă UV suport pentru amplasarea hotei robinet pentru vacuum robinet pentru gaze	Set de livrare Hota cu filtre Lampă de iluminare lampă UV suport pentru amplasarea hotei robinet pentru vacuum robinet pentru gaze

Safemate™ 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:
 - 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 *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 $\geq 99.995\%$ 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 (Material: steatite – Size: 5x20 - I²t: 121)	
Electrical insulating/protection class [IEC 61140]:	I	
IP protection degree:	Ordinary equipment (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:	indoor	
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 CONDITIONS		
Ambient temperature (°C):	from -5 to 45	
Relative humidity (%):	up to 90	
Atmospheric pressure (mbar):	from 800 to 1060	
1.6 WEIGHT AND DIMENSIONS		
Weight (kg):	260	360
Overall dimensions L x D x H (mm): (without support stand)	1380 x 780 x 1450	1990 x 780 x 1450
BioAir support stand authorized heights (mm):	690, 730, 770, 810	
Front aperture dimensions L x H (mm):	1165 x 195	1775 x 195
Working space dimensions L x D x H (mm):	1230 x 580 x 700	1840 x 580 x 700
Safe working area dimensions L x D (mm):	1030 x 350	1640 x 350
1.7 MATERIALS		
Main structure:	cold rolled steel, epoxy powder coated	
Walls inner surface of the working area:	stainless steel AISI 304 - SB finishing	
Working surface:	stainless steel AISI 304 - SB finishing	
Front window:	laminated safety glass	
1.8 PERFORMANCES		
Intended life of the equipment (years):	10	
Laminar Air Flow mean velocity [EN 12469](m/s):	0,35 ÷ 0,40	
Inflow Air Barrier mean velocity [EN 12469](m/s):	0,56 ±10%	
Exhaust Air flow rate (m³/h):	450 ±10%	600 ±10%
Exhaust Air flow ratio (%):	30 ±10%	
Apf - Aperture Protection Factor [EN 12469]: (Retention efficiency at front aperture)	≥1,0 x 10 ⁵	
Working space air cleanliness class [EN 14644-1]:	ISO 3	
Illuminance [EN 12469] (lux):	>750	
Sound level [EN ISO 3744] (dB[A]):	<65	
Vibration [EN 12469] (mm RMS):	<0,005	
Max increase inside cabinet in temperature from the ambient [EN 12469] (°C):	<5	
Leaktightness index of the cabinet housing [EN 12469]:	LI-C	
Cleanability index [EN 12469]:	CI-B	
Sterilizability index [EN 12469]:	SI-B	
1.9 DIMENSIONS AND FEATURES OF FILTERS		
LAF filter dimensions L x D x H (mm):	1219 x 610 x 68	1829 x 610 x 68
EXH filter dimensions L x D x H (mm):	610 x 457 x 68	915 x 457 x 90
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	

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	840	
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



Dasa-Rägister

IQ-0720-07

Certificato n.
Certificate 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.

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SGQ N° 052A

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 Organization for details regarding the exclusions 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.



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
S@feMate EZ 1.2
S@feMate EZ 1.8

CODICE - CODE
LDK400N
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	Prescrizioni di sicurezza per apparecchi elettrici di misura, controllo e per utilizzo in laboratorio. Parte 1: Prescrizioni generali.
IEC 61010-1:2010 +A1:2016	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	Bioteχνologie - 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

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Sistema di gestione Qualità certificato / Quality System certified
EN ISO 9001



Choose Scandinavian trust

Certificate of Approval

Nemko-044/ CTF Stage 1

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

The Scope: The standards and/or specialized test against which the Manufacturer's Testing Laboratory has been accepted to operate in the CB Scheme and/or the CB-FCS can be consulted through the following URL:
<https://www.iecee.org/dyn/www/f?p=106:33:0>

The above Manufacturer's Testing Laboratory facilities and staff have been assessed in accordance with the IECEE Testing at Manufacturers' Premises Programme and found to comply with the requirements of the latest Editions of the Basic Rules IECEE 01, Rules of Procedure IECEE 02 and the applicable requirements of ISO/IEC 17025 for the testing of electrotechnical equipment and components under the IECEE System, as specified in the IECEE Operational Documents

Issue Date: 2023-06-26

Expiration Date: 2025-06-06

Oslo 2023-06-26

Skule Moe
Product Certification Manager
Nemko Group

The validity of this approval is maintained through on-going Re-assessments.
Note: This Approval may be suspended or withdrawn in accordance with the Rules of Procedure of the IECEE.
This approval and schedule may only be reproduced in full.
This approval is not transferable.

The Status and authenticity of this approval may be verified by consulting the Customer Testing Facilities available on the IECEE public area

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


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