



SLOVENSKI STANDARD
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Biološke varnostne omare - 2. del: BSC razred II

Biological safety cabinets - Part 2: BSC class II

Biologische Sicherheitswerkbänke - Teil 2: BSC Klasse II

Postes de sécurité biologique - Partie 2: BSC de type II

Ta slovenski standard je istoveten z: prEN 12469-2

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Will supersede EN 12469:2000 (PART)

English Version

Biological safety cabinets - Part 2: BSC class II

Biotechnologie - Critères de performance pour les
postes de sécurité microbiologique

Biotechnik - Leistungskriterien für mikrobiologische
Sicherheitswerkbänke

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 332.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

This document (prEN 12469-2:2024) has been prepared by Technical Committee CEN/TC 332 “Laboratory Equipment”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document, together with prEN 12469-1:2024, prEN 12469-3:202X, prEN 12469-4:202X and prEN 12469-5:2024, will partially supersede EN 12469:2000.

prEN 12469-2:2024 includes the following significant technical changes with respect to EN 12469:2000:

- the structure has been changed to emphasize different classes of biological safety cabinets (BSC);
- additional test of the stability of protective functions;
- the text of the entire document has been revised and references have been updated.

prEN 12469 consists of the following parts, under the general title *Biological safety cabinets*:

- Part 1: Classes, terminology and basic requirements
- Part 2: BSC class II
- Part 3: BSC class III¹
- Part 4: BSC class I²
- Part 5: Installation, commissioning and routine testing

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¹ Under preparation.

² Under preparation.

prEN 12469-2:2024 (E)**Introduction**

Biological safety cabinets (BSC) are designed to reduce the risk to the operator when using biological materials. Dependent on type, they can protect the operator, the product, and the environment from biological aerosols.

BSC class I and class II are ventilated enclosures with an open front aperture.

A BSC class III is a fully enclosed workspace with gloves attached to the front port normally with an additional pass-through box attached.

A BSC class I provides operator and environment protection.

A BSC class II provides operator, product, and environment protection. In addition, it offers cross-contamination protection.

A BSC class III provides operator, environment and product protection. It is normally used in high level containment facilities for the highest risk group agents.

The type of BSC required is usually based on risk group, risk assessment and application.

This document describes the design and testing of these BSC for use in laboratories handling biological agents.

This document is a product standard. Occupational health and safety assessments methods are not included.

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1 Scope

This document specifies the specific requirements for class II BSC with respect to design, construction, safety and hygiene.

It sets the specific performance criteria for class II BSC for work with biological agents and specifies test procedures with respect to protection of the worker, the environment and product protection including cross-contamination.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

prEN 12469-1, *Biological safety cabinets - Part 1: Classes and basic requirements*

EN ISO 14644-7:2004, *Cleanrooms and associated controlled environments - Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments) (ISO 14644-7:2004)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in prEN 12469-1 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp/>
- IEC Electropedia: available at <https://www.electropedia.org/>

4 Tests

For the different test sets different requirements shall be verified. Table 1 gives an overview about the test sets and the requirements to be verified for the different sets.

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Table 1 — Requirements to be verified for different tests

Clause	Requirement: X = mandatory, R = recommended			
	Type test	Factory test	Commissioning	Routine test
5 Design and construction				
5.1 General	X		X	
5.2 Stability	X			
5.3 Ergonomics	X			
5.4 Lighting	X			
5.5 UV lamps	X			
5.6 Sound and vibration	X			
5.7 Glazing	X			
5.8 Carcass	X			
5.9 Filter System	X	X	X	X
5.10 Alarm Indicators and alarms				
5.10.1 Alarm indicators	X			
5.10.2 Alarms	X	X	X	X
5.11 Gas supply	X	R	X	R
5.12 Electrical installation	X	X	X	X
5.13 Stop/start of BSC	X	X	X	X
5.14 Connection to exhaust system	X		X	X
5.15 Cleanability	X			
5.16 Decontaminability	X			
5.17 Spillage tray	X			
5.18 Intake grille	X			
6 Airflows				
6.2 Downflow	X	X	X	X
6.3 Inflow	X	X	X	X
6.4 Disturbance of airflows	X		X	X
7 Protective functions				
7.2 Operator protection ^a	X		X	X
7.3 Product protection	X			
7.4 Cross-contamination protection	X			
7.5 Stability of the protective functions	X			
8 Accompanying documents ^b				
8.1 Operating manual	X	X	X	X
8.2 Equipment logbook	X	X	X	X
8.3 Brief instruction for use	X	X	X	X
9 Marking	X	X	X	X
^a A1 for type test, A2 for commissioning and routine test				
^b for type test check content, for other test check if the documents are available				

5 Design and construction

5.1 General

The general design and construction shall be in accordance with prEN 12469-1.

5.2 Stability

The stability shall be in accordance with prEN 12469-1.

5.3 Ergonomics

The ergonomics shall be in accordance with prEN 12469-1.

5.4 Lighting

5.4.1 General

The lighting shall be in accordance with prEN 12469-1.

5.4.2 Testing

The lighting shall be tested according to prEN 12469-1.

For testing the following measuring grid shall be used: the first measuring line on the work surface shall start 10 cm behind the intake slots. Starting point from left to right is 15 cm from the side walls. Divide the lines into equally spaced sections with a maximum of 20 cm. The second line shall be 20 cm behind the first line.

5.5 UV lamps

UV lamps shall be in accordance with prEN 12469-1.

5.6 Sound and vibrations

Sound and vibration levels shall be in accordance with prEN 12469-1.

5.7 Glazing

5.7.1 General

The glazing material and construction shall be in accordance with prEN 12469-1.

5.7.2 Testing of the front window

5.7.2.1 Test procedure

Set the sash to the test sash position. Disconnect one of the suspension devices of the sash.

Repeat the test with the other suspension device.

5.7.2.2 Acceptance criteria

If the sash moves it shall not endanger the operator in case of first fail.

5.8 Carcass

5.8.1 General

The carcass shall be in accordance with prEN 12469-1.

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For a BSC class II the carcass includes the exterior surfaces, welds, gaskets and seals etc. The carcass shall be leak tight.

There are two methods to check leak tightness. The two methods are described in 5.8.2.1 and 5.8.2.2.

5.8.2 Testing**5.8.2.1 Pressure decay test****5.8.2.1.1 Material and Equipment**

- Manometer, capable of reading in the range 0 Pa to 500 Pa with an accuracy of $\pm 2\%$
- Plates to seal opening as needed (provided by the manufacturer).

5.8.2.1.2 Test procedure

The BSC is tested for leakage by subjecting it to an internal pressure.

- Seal all openings in the cabinet by any convenient means.
- Attach a manometer to the test area to indicate the interior pressure.
- Pressurize the cabinet to an internal positive pressure of 250 Pa + 20 Pa.
- Turn off the pressurizing air and measure the pressure after 1 min.

5.8.2.2 Constant pressure test**5.8.2.2.1 Material and Equipment**

- Volumetric flow meter capable of a reading in the range 0 to 2 m³/h with an accuracy of $\pm 7\%$
- Manometer, capable of reading in the range 0 Pa to 500 Pa. With an accuracy of $\pm 2\%$
- Plates to seal any opening as needed (provided by the manufacturer)

5.8.2.2.2 Test procedure

- Seal all openings in the cabinet by any convenient means.
- Attach a manometer to the test area to indicate the interior pressure.
- Pressurize the cabinet to an internal positive pressure of 250 Pa + 20 Pa.

The volumetric flow meter is installed in the hose via which the test air is fed into the cabinet (positive pressure test) For air feed, a very finely controllable positive pressure connection is required. The introduced flow rate is regulated in order to maintain the positive pressure at its specific value. This flow rate divided by the net volume of the cabinet corresponds to the hourly leak rate.

To avoid the effect of atmospheric pressure and temperature changes, the measurement shall be less than 10 min long.

5.8.2.3 Acceptance criteria

The leak tightness shall not be less than class 4 according to EN ISO 14644-7:2004, Table E.1 (see Table 2).

Table 2 — Comparison of classification of containment enclosures according to their hourly leakage rate and pressure loss

Class	Hourly leak rate R_h h^{-1}	Calculated pressure loss per minute ^a Δp Pa	Calculated leakage rate per 1 m ³ volume of the cabinet R_V l/min
1	$\leq 5 \cdot 10^{-4}$	0,84	$8,3 \cdot 10^{-3}$
2	$< 2,5 \cdot 10^{-3}$	4,2	0,041
3	$< 10^{-2}$	16,9	0,167
4	$< 10^{-1}$	168,9	1,67

^a At atmospheric pressure (101 325 Pa).
NOTE The calculation is based on requirements of EN ISO 14644-7:2004, Table E.1

5.9 Filter system

The filter system shall be in accordance with prEN 12469-1.

5.10 Alarm indicators and alarms

5.10.1 Alarm indicators

The alarm indicators shall be in accordance with prEN 12469-1.

5.10.2 Alarms

The alarms shall be in accordance with prEN 12469-1.

For class II BSC the critical parameters for alarms are:

- downflow: low and high alarm
- inflow: low and if possible high alarm
- sash not in working position

5.11 Gas supply

General requirements for the gas supply shall be in accordance with prEN 12469-1.

5.12 Electrical installation

The electrical installation shall be in accordance with prEN 12469-1.

5.13 Stop / start of BSC

The stop / start shall be in accordance with prEN 12469-1.

5.14 Connection to exhaust systems

The connection to an exhaust system shall be in accordance with prEN 12469-1.

5.15 Cleanability

The cleanability shall be in accordance with prEN 12469-1.

prEN 12469-2:2024 (E)**5.16 Decontaminability**

The decontaminability shall be in accordance with prEN 12469-1.

5.17 Intake grille

The design should ensure that the intake grille cannot be obstructed by operator's arms.

The delivery area for the air to the working space should be without interposed projections or cavities that could interfere with containment performance.

5.18 Height of the front aperture

The height of the front aperture has an influence on the inflow, the airflow balance and the protective functions. Manufacturers optional heights of front apertures shall be type tested. The sash height(s) shall be stated on the ID plate on the BSC.

6 Velocity**6.1 General**

The target values for the airflow velocities shall ensure proper use as intended with regard to operator, environmental, product and cross-contamination protection as described in Annex A (A.1), Annex B and Annex C. In a BSC class II these protection functions depend on the velocity and the ratio of the downflow and inflow.

6.2 Downflow**6.2.1 General**

The downflow velocity specified by the manufacturer shall ensure that the intended protection function of the BSC is met. The manufacturer's specification shall be noted on the ID plate of the unit.

6.2.2 Testing**6.2.2.1 Material and equipment**

For airflow velocity measurements an anemometer with the specifications given in Table 3 shall be used.

Table 3 — Specification of anemometers

Item	Minimum requirements	Measuring range
Resolution	0,01 m/s	0 m/s to 1,00 m/s
Accuracy	$\pm(0,02 \text{ m/s} + 5 \% \text{ of mv})$	0,20 m/s to 1,00 m/s
For downflow velocities < 0,2 m/s the manufacturer shall specify the equipment needed.		

6.2.2.2 Test procedure

The below description, including Figure 1, specifies the minimum number of measuring points. An alternative measuring grid may be used as long as the minimum number of measuring points is more than described and the points are evenly distributed over the work surface.

The measuring probe of the anemometer shall not be hand-held during downflow measurements.

The measurements shall be done in a horizontal plane at 10 cm above the bottom edge of the sash in its normal operating position.