KAVALIER

# CERTIFICATE OF CONFORMITY

208/22

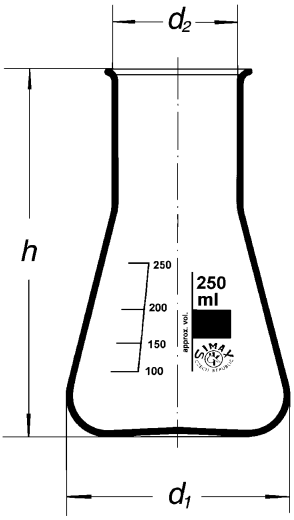
*Issuer´s name/ producer:* **KAVALIERGLASS, a.s.**
*Issuer´s address/Producer:* **Křížová 1018/6, Prague 5**
**office: Sklářská 359, 285 06 Sázava, Czech Republic**

*Object of the declaration:* **FLASK ERLENMEYER, wide neck**

| Catalogue Nr. | Product IDN | Capacity/ ml | d1 [mm] | d2 [mm] | h [mm] |
|---|---|---|---|---|---|
| 25 | 1632411106025 | 25* | 42 | 32 | 70 |
| | 1632411106050 | 50 | 51 | 34 | 85 |
| | 1632417106100 | 100 | 64 | 34 | 110 |
| | 1632417106200 | 200* | 79 | 50 | 131 |
| | 1632417106250 | 250 | 85 | 50 | 140 |
| | 1632417106300 | 300* | 87 | 50 | 156 |
| | 1632417106500 | 500 | 105 | 50 | 175 |
| | 1632417106940 | 1000 | 131 | 50 | 220 |
| | 1632417106950 | 2000* | 153 | 72 | 280 |

** outside the Regulation*

## Scheme of the glass item


| **Material specification:** | | |
|---|---|---|
| **Erlenmeyer Flask** | clear | Borosilicate glass SIMAX® |
| **Print** | white | in fired-on, chemically resistant ceramic enamel |
| | | |
| **Purpose of use** | Mixing liquids, suitable for thermic operations, wide neck simplifies filling and cleaning | |

## The object of the certificate described above is in conformity with the requirements of the following standards and regulations:

**Glass characteristics:**

- ISO 3585 Borosilicate glass 3.3 – Properties

  - Chemical durability (art. 4.1, 4.2, 4.3, 4.4)
  - Physical properties (art. 5.1, 5.2, 5.3, 5.4, 5.5, 5.6)

- Glass containers for pharmaceutical use

  - Eur. Ph 10$^{th}$ Edition -3.2.1 Glass Type I.

- ISO 24450:2005 Laboratory glassware — Wide-necked boiling flasks

  - Maximum permissible errors in dimensions fulfill the values specified in Table 1 - ISO 24450.

Table 1 – ISO 24450

| **Dimensions of conical flasks** | | | |
|---|---|---|---|
| **Nominal volume [ml]** | **External diameter of body at widest point [±mm]** | **External diameter of neck [±mm]** | **Overall height [±mm]** |
| 50 | 51±1 | 34±1,5 | 85±3 |
| 100 | 64±1,5 | 34±1,5 | 105±3 |
| 250 | 85±2 | 50±2 | 140±3 |
| 500 | 105±2 | 50±2 | 175±4 |
| 1000 | 131±3 | 50±2 | 220±4 |

**No heavy metals (lead, cadmium, mercury and hexavalent chromium):**

- Regulation (EC) No. 987/2008 of 8 October 2008 amending Regulation (EC) No. 1907/2006 – REACH as regards Annexes IV and V – glass was exempted from the obligation to register.

- **Chemical characteristics of borosilicate glass (**approximate values**)**

| Component | Content (percentage by weight) |
|---|---|
| $SiO_2$ | 80,3% |
| $B_2O_3$ | 13,0% |
| $Al_2O_3$ | 2,4% |
| $Na_2O + K_2O$ | 4,3% |

## Characteristics of Borosilicate glass SIMAX®

### Dossier of extractables and leachables studies:

- **Acid resistance** — Class I. (to ISO 1776)
- **Hydrolytic resistance** — Class I. (HGB1 to ISO 719; HGA1 to ISO 720)
- **Acid resistance** — ISO 1776
- **Resistance to attack by a boiling aqueous solution of mixed alkali** — Class A2 (to ISO 695)

- **Coefficient of mean linear thermal expansion α: 3,3 x$10^{-6}$ $K^{-1}$ (to ISO 7991; 20/300 °C)**

- **Pharmaceutical use**

| | *European Pharmacopoeia (EP)* | *US Pharmacopoeia (USP)* | *Japanese Pharmacopoeia (JP)* |
|---|---|---|---|
| **Glass** | Eur. Ph.$10^{th}$ – 3.2.1 | USP <660> | JP16 |

**Supporting data:**

| **TEST / European Pharmacopoeia $10^{th}$, Art. 3.2.1** | **UNIT** | **LIMIT** | **RESULT** |
|---|---|---|---|
| **Hydrolytic resistance - inner surfaces, test A** | ml 0,01 mol/l HCl/100ml of leachate | **max 0,40** | **0,04** |
| **Hydrolytic resistance - glass grains, test B** | mol 0,02/l HCl/g | **max 0,1** | **0,038** |
| **Arsenic content** | mg As/g | **max 0,1** | **< 0,001** |

*Additional information:*

**The producer confirms hereby that the characteristics, measures and accuracy of the products listed above are in full conformity with the provisions of the standard.**

**The producer also declares that the products are safe when used in usual and proper way.**

The producer has installed the Quality Assurance System according to ISO 9001 and thus guarantees that all products delivered to the market are in full conformity with the technical documentation and with all fundamental requirements to such products.
Certificate No. 04 100 940602 issued by TÜV CERT, Certification Body at TÜV NORD CERT GmbH.

The certificate is issued for the customer: **AUXILAB S.L.**

Sázava, 19. 05. 2022
*Place and date of issue*

Ing. Kristýna Machová
*Project Quality Engineer*

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