



KAVALIER

DECLARATION OF COMPLIANCE

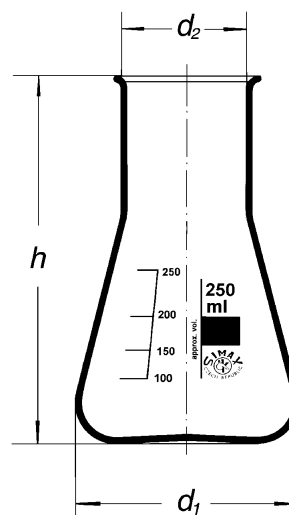
Issuer's name/ producer: **KAVALIERGLASS, a.s.**
 Issuer's address/Producer: **Křížová 1018/6, Prague 5**
office: Sklářská 359, 285 06 Sázava, Czech Republic

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

<u>Catalogue Nr.</u>	<u>Product IDN</u>	<u>Capacity/ ml</u>	<u>d1 [mm]</u>	<u>d2 [mm]</u>	<u>h [mm]</u>
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 10th 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 ₂ O ₃	13,0%
Al ₂ O ₃	2,4%
Na ₂ O + K ₂ O	4,3%

Characteristics of Borosilicate glass SIMAX®

- Acid resistance Class I. ISO 1776
- Hydrolytic resistance Class I. HGB1 to ISO 719;
HGA1 to ISO 720
- Alkali resistance Class II. ISO 695
- Coefficient of mean linear thermal expansion $\alpha: 3,3 \times 10^{-6} \text{ K}^{-1}$ ISO 7991; (20/300 °C)
- Pharmaceutical use

	<i>European Pharmacopoeia (EP)</i>	<i>US Pharmacopoeia (USP)</i>	<i>Japanese Pharmacopoeia (JP)</i>
Glass	Eur. Ph.10 th – 3.2.1	USP <660>	JP16

Supporting data:

TEST / European Pharmacopoeia 10, 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	µg 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: -

Sázava, 08. 06. 2021
Place and date of issue

Ing. Kristýna Machová
Project Quality Engineer

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