



**KAVALIER**

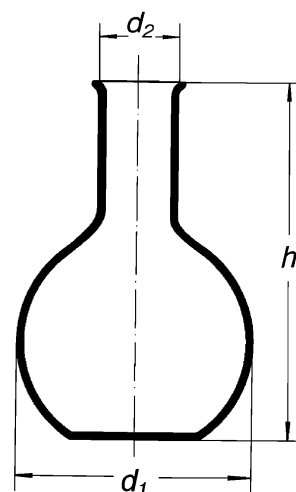
# DECLARATION OF COMPLIANCE

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: **FLASKS FLAT BOTTOM,**  
**narrow neck, with rim**

<u>Catalogue Nr.</u>	<u>Product IDN</u>	<u>Capacity/ ml</u>	<u>d1 [mm]</u>	<u>d2 [mm]</u>	<u>h [mm]</u>
10	1632411117050	50	51	22	100
	1632411117100	100	64	22	110
	1632411117250	250	85	34	140
	1632411117500	500	105	34	170
	1632411117940	1000	131	42	200
	1632411117950	2000	166	50	250
	1632411117954	4000	207	50	300
	1632411117958	6000	236	65	340
	1632411117966	10000	279	65	400

## Scheme of the glass item



<b>Material specification:</b>		
<b>Flask</b>	clear	Borosilicate glass SIMAX®
<b>Print</b>	white	in fired-on, chemically resistant ceramic enamel
<b>Purpose of use</b>	Laboratory glassware Suitable for thermic operations	

**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<sup>th</sup> Edition -3.2.1 Glass Type I.
- ČSN 704041: 1998 / Z2 Laboratory glassware - Flasks with round and flat bottoms
  - Maximum permissible errors in dimensions fulfill the values specified in Table 1 - ČSN 704041.

Table 1 – ČSN 704041

<b>Dimensions of flasks, flat bottom</b>			
<b>Nominal volume [ml]</b>	<b>External diameter of body at widest point [±mm]</b>	<b>External diameter of neck [±mm]</b>	<b>Overall height [±mm]</b>
50	51±1	22±1	100±3
100	64±1,5	22±1	110±3
250	85±2	34±1,5	140±3
500	105±2	34±1,5	170±4
1000	131±3	42±2	200±4
2000	166±3	50±2	250±4
4000	207±3	50±2	300±5
6000	236±3	65±2,5	340±5
10000	279±4	65±2,5	400±6

**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)**

<b>Component</b>	<b>Content (percentage by weight)</b>
SiO <sub>2</sub>	80,3%
B <sub>2</sub> O <sub>3</sub>	13,0%
Al <sub>2</sub> O <sub>3</sub>	2,4%
Na <sub>2</sub> O + K <sub>2</sub> 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>
<b>Glass</b>	Eur. Ph.10 <sup>th</sup> – 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	$\mu\text{g As/g}$	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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