KAVALIER

CERTIFICATE OF CONFORMITY

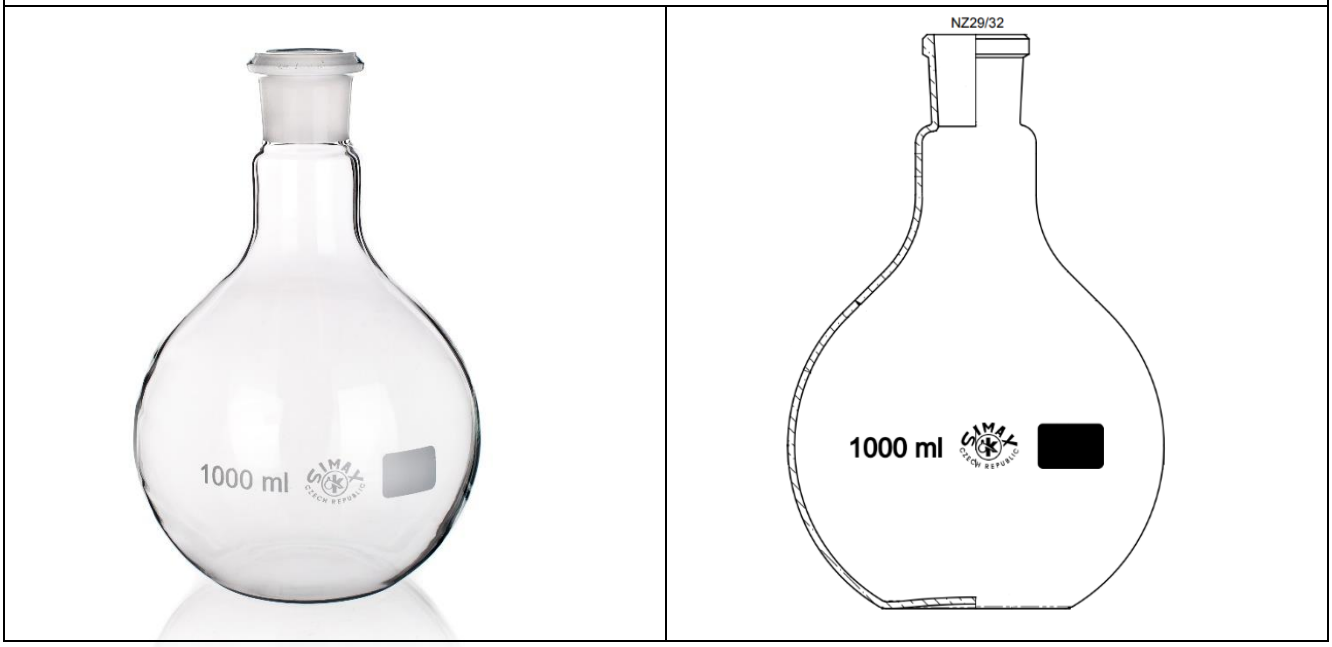
213/22

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: **FLASKS FLAT BOTTOM, with SJ**

Catalogue Nr.	Product IDN	Capacity/ ml	d [mm]	h [mm]	SJ
8003	1632426217102	100	64	110	29/32
	1632426217250	250	85	140	29/32
	1632426217500	500	105	170	29/32
	1632426217940	1000	131	200	29/32
	1632426217941	1000	131	200	45/40

Scheme of the glass item



Material specification:		
Flask	clear	Borosilicate glass SIMAX®
Print	white	in fired-on, chemically resistant ceramic enamel
Print on the neck SJ	green – PANTONE 349C	in fired-on, chemically resistant ceramic decal
Purpose of use	Laboratory glassware, the flat bottom provides for stability without supporting ring	

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.
- EN ISO 24450 Laboratory glassware - Wide-necked boiling flasks
  - Maximum permissible errors in dimensions fulfill the values specified in Table 1 - ČSN 704041.

Table 1 – ČSN 704041

Dimensions of flasks, flat bottom			
Nominal volume [ml]	**External diameter of body at widest point [±mm]**	**External diametr of neck [±mm]**	**Overall height [±mm]**
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**)**

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 x10^{-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

KAVALIERGLASS, a.s.
Křižová 1018/6, 150 00 Praha 5
office: Sklářská 359, 285 06 Sázava
Czech Republic
IČ: 474 68 815
-61-