



KAVALIER

CERTIFICATE OF CONFORMITY

209/22

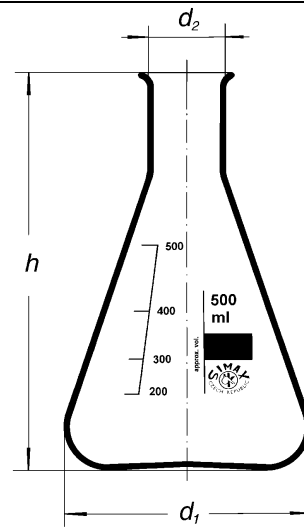
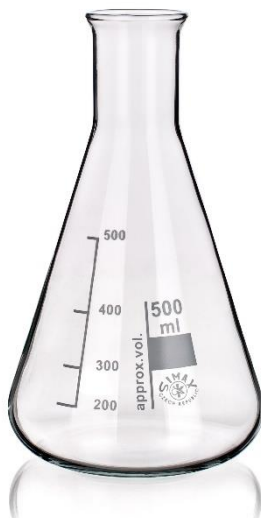
Issuer's name/ producer:
Issuer's address/Producer:

KAVALIERRGLASS, a.s.
Křížová 1018/6, Prague 5
office: Sklářská 359, 285 06 Sázava, Czech Republic

Object of the declaration: **FLASK ERLLENMEYER, narrow 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>
24	1632411119025	25	42	22	75
	1632411119050	50	51	22	90
	1632417119100	100	64	22	105
	1632417119200	200	79	34	135
	1632417119250	250	85	34	145
	1632417119300	300	87	34	160
	1632417119500	500	105	34	180
	1632417119940	1000	131	42	220
	1632417119950	2000	166	50	280
	1632411119952	3000	187	50	310
	1632411119956	5000	220	50	365
	1632411119968	20000	610	380	370

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	

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 1773:1997. Laboratory glassware — Narrow-necked boiling flasks
 - Maximum permissible errors in dimensions fulfill the values specified in Table 1 - ISO 1773.

Table 1 – ISO 1773

Dimensions of conical flasks			
Nominal volume [ml]	External diameter of body at widest point [±mm]	External diameter of neck [±mm]	Overall height [±mm]
25	42±1	22±1	75±3
50	51±1	22±1	90±3
100	64±1,5	22±1	105±3
250	85±2	34±1,5	145±3
500	105±2	34±1,5	180±4
1000	131±3	42±2	220±4
2000	166±3	50±2	280±4
3000	187±3	50±2	310±5
5000	220±3	50±2	365±5

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®

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 : $3,3 \times 10^{-6} \text{ K}^{-1}$ (to 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 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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