



KAVALIER

CERTIFICATE OF CONFORMITY

211/22

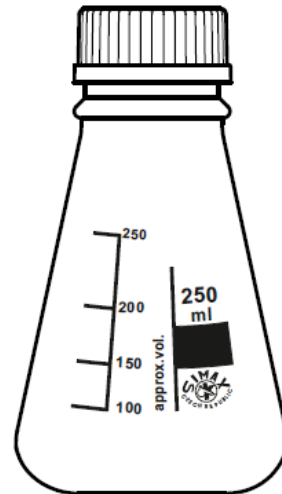
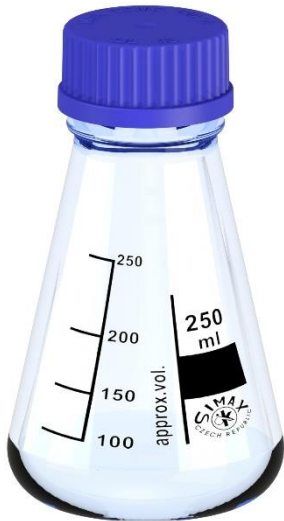
Issuer's name/ producer:
Issuer's address/Producer:

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

Object of the declaration: **BOTTLES ERLENMEYER, GL thread**

<u>Catalogue Nr.</u>	<u>Product IDN</u>	<u>Capacity/ ml</u>	<u>d [mm]</u>	<u>h [mm]</u>	<u>GL thread</u>
8023 GL	1632414941250	250	85	150	
	1632414941500	500	105	185	GL 45
	1632414941940	1000	131	225	
	1632414941950	2000	160	290	

Scheme of the glass item



Material specification:

Erlenmeyer Flask	clear	Borosilicate glass SIMAX®
Screw cap	blue	PP BORMED™ HD850MO
Print	white	in fired-on, chemically resistant ceramic enamel
Purpose of use	Substance storage, preparation of medias and cultivation, 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.
- ČSN 70 4030 Glass boiling flasks — General technical requirements

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%

- **Chemical characteristics (acc. to Regulation No 1907/2006/EC):**

Composition:	CAS No.	EINECS No.	Component:	Concentration /Percent:
	65997-17-3	266-046-0	Glass, oxide, chemicals	100%

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, 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

Screw Cap with a Pouring Ring Eur. Ph.9 – 3.1.3; based on the statement of the supplier

- **Storage conditions of concentrated sulfuric acid in reagent bottle with screw cap GL45**

Diluted sulfuric acid up to 50% is alright, even at long-term exposure to temperatures up to 70°C. More concentrated acid, especially at higher temperatures, causes changes in mechanical properties of the lid. Concentration above 80% is unsuitable, because it causes oxidative degradation of the polypropylene of the lid.

- **Temperature resistance**

Glass The maximum permissible short-term operating temperature is 500°C
The maximum thermal shock resistance is ΔT=100 K.

Screw Cap with a Pouring Ring -40°C to +140°C

- **Sterilization***

Hot air sterilization, in the oven up to 140°C
Steam sterilization, in an autoclave 121°C/ 20 min
134°C/ 10 min

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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