



KAVALIER

DECLARATION OF COMPLIANCE

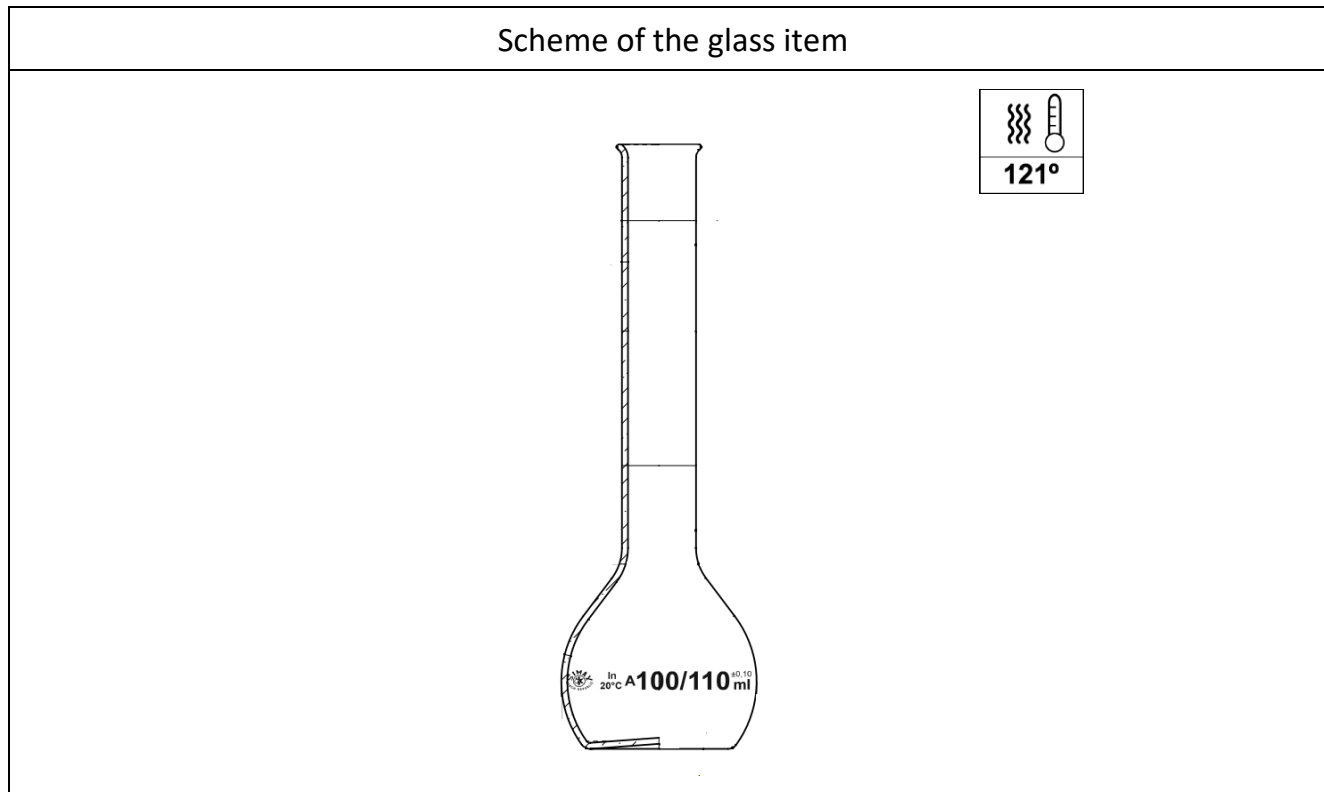
559/24

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

Object of the declaration: **FLASKS VOLUMETRIC, SUGAR ANALYSIS,**
two marks

<u>Product IDN & Description</u>	<u>Catalog No.</u>	<u>Tolerance [±ml]</u>	<u>Marking [ml]</u>	<u>d₁ [mm]</u>	<u>d₂ [mm]</u>	<u>h [mm]</u>
1509	1632431510025	0.06	50 + 55	47	18	155
	1632431510030	0.1	100 + 110	58	22	180
	1632431510037	0.15	200 + 220	73	24	200

Scheme of the glass item



Material specification:		
Flask volumetric	clear	Borosilicate glass SIMAX®
Print on the body of the flask	white	in fired-on, chemically resistant ceramic enamel
Purpose of use	laboratory volumetric glassware A two-mark flask designed for the analysis of sugar solutions.	

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 10.3-3.2.1 Glass Type I.
- BS 675:1953 Specification for sugar flasks

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 (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%

- **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

- **Sterilization**

Hot air sterilization, in the oven	up to 140 °C
Steam sterilization, in an autoclave	121 °C/ 20 min/ 2,05 bar
	134 °C/ 10 min/ 3,04 bar

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. 3258 100 23 52 0132 issued by TÜV CERT, Certification Body at TÜV NORD CERT GmbH.

The certificate is issued for the customer: **AUXILAB S.L.**

Sázava, 29. 10. 2024
Place and date of issue

Ing. Kristýna Machová
Project Quality Engineer

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