CERTIFICATE OF CONFORMITY

KAVALIER

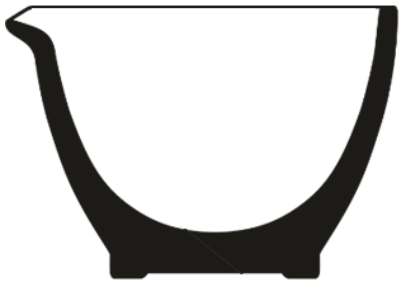
376/25

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

Object of the declaration: **MORTARS WITH A POUR-OUT LIP, inside glazed**

Cat. No. & Description	Product IDN	Mortar [mm]		
		d_1 [mm]	d_2 [mm]	h [mm]
2231 clear & inside glazed	1632538151080	80	50	60
	1632538151100	100	60	75
	1632538151120	120	70	90
	1632538151150	150	85	110
	1632538151200	200	120	135

Scheme of the glass item



Material specification:		
Mortar	clear; glazed	Borosilicate glass SIMAX®
Pestle		
Purpose of use	Laboratory glassware Ideal for preparing compounds, mixing and grinding powders	

The object of the certificate described above is in conformity with the requirements of the following Standards and Regulations:

- **General Product Safety Regulation 2023/988 (GPSR)** of 13 December 2024 Ensuring product safety in the EU

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.

FOOD CONTACT:

- Commission Regulation (EU) No. 2023/2006

Good manufacturing practice for materials and articles intended to come into contact with food

- Regulation EC No 1935/2004 of 27 October 2004

Directive on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

- Regulation of Czech Health Ministry Decree No. 38/2001 Coll.

Directive on articles intended to come into contact with foodstuffs

- Directive 84/500EEC of 15 October 1984

Directive on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs.

- ISO 7086-1:2019 Glass hollowware in contact with food

Release of lead and cadmium – Part 1: Test method

- ISO 7086-2:2000 Glass hollowware in contact with food

Release of lead and cadmium – Part 2: Permissible limits

- ISO 719:2000 Glass - Hydrolytic resistance of glass grains at 98 °C

Method of test and classification

- ASTM E438 Standard Specification for Glasses in Laboratory Apparatus

Classification, chemical requirements of the glass

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%

- **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®

- **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 α: 3,3 x10^{-6} K^{-1}** — ISO 7991; (20/300 °C)
- **Pharmaceutical use**

	European Pharmacopoeia (EP)	*US Pharmacopoeia (USP)*	*Japanese Pharmacopoeia (JP)*
Glass	Eur. Ph.10th – 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**

- **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, 19. 06. 2025
Place and date of issue

Ing. Kristýna Machová
Project Quality Engineer

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