KAVALIER

CERTIFICATE OF CONFORMITY

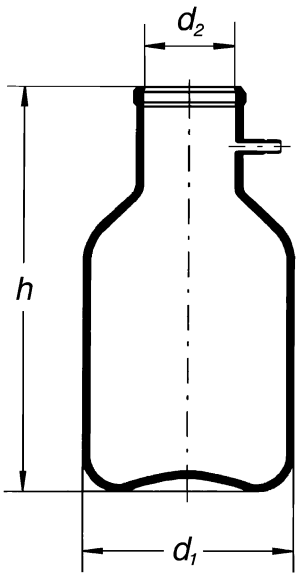
71/24

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: **FLASKS FILTERING, with glass side hose**

Catalogue Nr.	Product IDN	Customer Code	Capacity [ml]	h [mm]	d_1 [mm]	d_2 [mm]
2420	1632412022956	PJH011	5000	360	185	80

Scheme of the glass item



Material specification:		
Flask	clear	Borosilicate glass SIMAX®
Print	white	in fired-on, chemically resistant ceramic enamel
Purpose of use	Laboratory glassware Suitable for the use of vacuum for accelerated filtering Typical use: filtering of liquids	

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)

- ISO 4794 Laboratory glassware — Methods for assessing the chemical resistance of enamels used for colour coding and colour marking

- EN ISO 6556:2012 - Laboratory glassware — Filter flasks
  Series A filter flasks of conical shape shall comply with the dimensions given in Table 1. The vacuum connection shall be placed just at, or below, the cylindrical part of the neck.

Table 1 EN ISO 6556:2012

Nominal size [ml]	**d_1 [mm]**	**d_2 [mm]**	**h [mm]**	**r min. [mm]**	**s_1 min. [mm]**	**s_2 min. [mm]**
100	70±3	24±3	105±3	12	1,7	1,2
250	85±3	35±3	155±3	12	2,4	1,3
500	105±3	35±3	185±3	15	3	1,4
1000	135±3	45±3	230±3	20	3,8	1,6
2000	165±3	60±3	255±3	35	4,2	1,8

- Glass containers for pharmaceutical use

  - Eur. Ph 10th Edition -3.2.1 Glass Type I.

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_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. 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.**

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Sázava, 10. 01. 2024
Place and date of issue

Ing. Kristýna Machová
Project Quality Engineer