

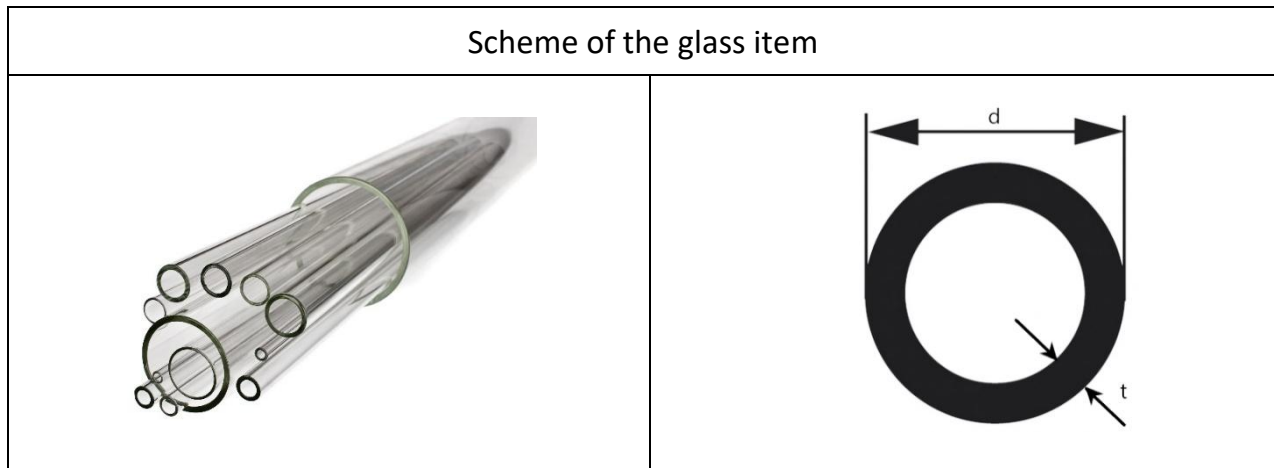


# DECLARATION OF COMPLIANCE

**KAVALIER**

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

*Object of the declaration:* **GLASS TUBES; RODS; CAPILLARIES**



*Material:* **Borosilicate glass SIMAX<sup>®</sup>, glass with high thermal and chemical resistance  
Glass Type I**

*Country of origin:* **Czech Republic**

*Purpose of use:* **Application in technical, pharmaceutical, laboratory or food industry**

The object of the declaration is in conformity with 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)
- ISO 4803:2021 Laboratory glassware – Borosilicate glass tubing

**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 719:2023 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 – EU REACH Regulation  
Products do not release Substances of Very High Concern (SVHCs) above their respective threshold values listed in SVHC Candidate List, published by European Chemicals Agency (ECHA) as a part of REACH Regulation with latest publication date 04<sup>th</sup> February 2026.
- RoHS  
Directive 2011/65/EC (RoHS II), amended by 2015/863/EC (RoHS III), on the restriction of the use of certain hazardous substances in electrical and electronic equipment, Annex II – extension of limitation regarding 4 additional substances.
- CMR/ ED substances  
We hereby certify that the borosilicate glass SIMAX® does not contain any of the CMR/ ED substances.
- Regulation (EU) 745/217 Medical Device Regulation (EU MDR)  
Not applicable, we are not manufacturer of medical devices.
- Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h)

We hereby certify that none of the five restricted PBT substances listed below are intentionally added to our products.

- Phenol, isopropylated phosphate (PIP 3:1)
- Decabromodiphenylether (DecaBDE)
- 2,4,6-Tris(tert-butyl) phenol (2,4,6-TTBP)
- Hexachlorobutadiene (HCBd)
- Pentachlorothiophenol (PCTP)

- BSE/ TSE

Glass is free from BSE and TSE. Glass is manufactured by using raw material of non-animal origin, does not contain meat products and does not come in contact with meat products.

- The FDA classifies glass in general as GRAS (Generally Recognized as Safe).

**Origin:** Federal Register/Vol 48, No. 27/Feb. 08.1983/page 5718, Rules and Regulations

**Citation:** “The agency has traditionally considered materials such as ceramics, glass, and stainless steel as GRAS for food-contact use, based on their safe history of common use as food-contact materials before 1958. However, because the use of these materials has been so widespread, the agency has never considered it necessary to list these materials as GRAS”

# TECHNICAL REQUIREMENTS ACCORDING TO PURPOSE OF USE

## Characteristics of Borosilicate glass SIMAX®

SIMAX® is notable for very high thermal shock resistance. Because of its high hydrolytic resistance, SIMAX® is a neutral glass and is classed as a Glass Type I, it complies with requirements of the European pharmacopoeia and is also suitable for use with foodstuffs.

- **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  $\alpha$ :  $3,3 \times 10^{-6} \text{ K}^{-1}$**  ISO 7991; (20/300 °C)
- **Glass containers for pharmaceutical use**
  - Eur. Ph 10<sup>th</sup> Edition - 3.2.1 Glass Type I.
  - USP <660> Glass Type I.
  - 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	mg As/g	max 0,1	< 0,001

- **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)** ASTM E438

Component	Content (percentage by weight)
SiO <sub>2</sub>	80,3%
B <sub>2</sub> O <sub>3</sub>	13,0%
Al <sub>2</sub> O <sub>3</sub>	2,4%
Na <sub>2</sub> O + K <sub>2</sub> O	4,3%

- **Chemical stability:** Stable

### Additional information:

These products are made of borosilicate glass, which does not harm the human health. Its characteristics are constantly tested and comply fully with the standard ISO 3585 Borosilicate glass 3.3 –Properties.

The producer 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 for 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:

Sázava, 24. 02. 2026  
Place and date of issue

Ing. Kristýna Machová  
Project Quality Engineer

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