



# 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: **LABORATORY, TECHNICAL GLASS**

Material: **Borosilicate glass SIMAX®, 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 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<sup>th</sup> Edition - 3.2.1 Glass Type I.
  - USP <660> Glass Type I.

**FOOD CONTACT:**

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



## 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.

### 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  $\alpha$ :  $3,3 \times 10^{-6} \text{ K}^{-1}$  (to ISO 7991; 20/300 °C)**
- **Pharmaceutical use**

<i>European Pharmacopoeia (EP)</i> Eur. Ph.10 <sup>th</sup> – 3.2.1	<i>US Pharmacopoeia (USP)</i> USP <660>	<i>Japanese Pharmacopoeia (JP)</i> JP16
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### Supporting data:

TEST / European Pharmacopoeia 10 <sup>th</sup> , 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:

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 to the customer:

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

Ing. Kristýna Machová  
Project Quality Engineer

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