PRODUCT DATA SHEET

KAVALIER

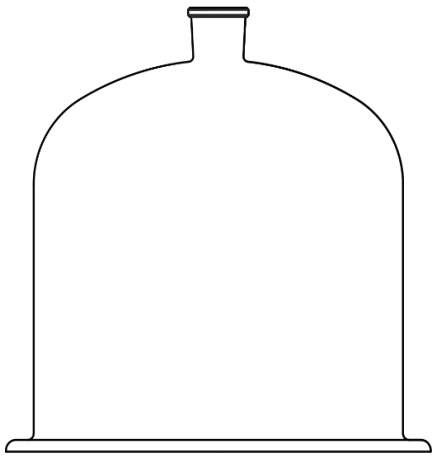
378/25

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: **VACUUM BELL JARS,**
with ground flange, neck SJ

Product IDN & Description		Catalog Nr.	d [mm]	h [mm]	SJ
2874	clear bottles	1632415502153	150	200	29/32
		1632415502154	150	250	29/32
		1632415502205	200	300	29/32

Scheme of the glass item



Material specification:		
Bell Jar	clear	Borosilicate glass SIMAX®
Stopcock for bell jars SJ 34/35		
Nut	blue	PP MOSTEN MA230
Decal on the stopcock	green	in fired-on, chemically resistant ceramic decal
Purpose of use	Vacuum operations Neck with standardized ground joint	

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

- **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

- **ČSN 70 4309**

Laboratory glass – Thick-walled jars. General technical requirements.

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 Borosilicate glass SIMAX® (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®

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)*

Supporting data:

TEST / European Pharmacopoeia 10th, 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**

- **Temperature resistance**

The recommended permissible temperature is 300 °C. This temperature may be exceeded for a short period.

- **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

- **Pressure resistance**

As standard, tests are carried out at normal pressure. Conducting the experiment under vacuum (negative pressure) can have a significant impact on the reaction process.
In order to be able to observe these effects in the coarse and fine vacuum range, a vacuum experimental plate and a plane flange bell (also known as an air pump bell) are required.

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

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

PRODUCT DATA SHEET

KAVALIER

380/24

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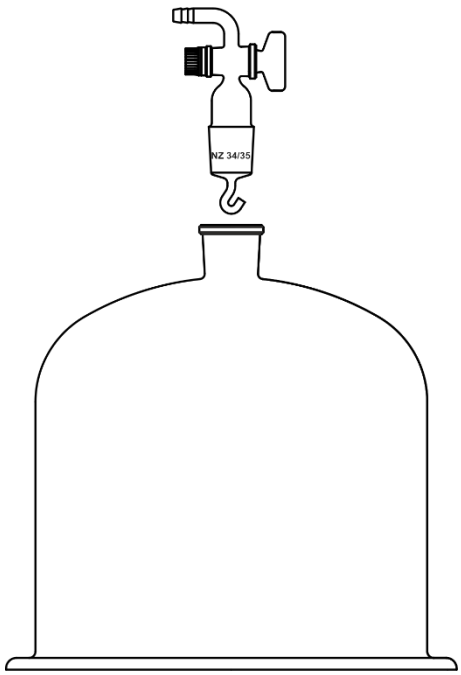
Issuer´s address/Producer: **Křížová 1018/6, Prague 5**
Production plant: Sklářská 359, 285 06 Sázava, Czech Republic

Object of the declaration: **VACUUM BELL JARS,**
with ground-N Stopcock

Product IDN & Description		Catalog Nr.	d [mm]	h [mm]	SJ
2876	clear bottles	1632415502154	300	300	34/35

Scheme of the glass item



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- **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)*
Eur. Ph.10^{th} – 3.2.1	USP <660>	JP16

Supporting data:

TEST / European Pharmacopoeia 10th, Art. 3.2.1	UNIT	LIMIT	RESULT
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The certificate is issued for the customer: **AUXILAB S.L.**

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

Sázava, 25. 06. 2024
Place and date of issue

Ing. Kristýna Machová
Project Quality Engineer