CERTIFICATE OF CONFORMITY

KAVALIER

431 /25

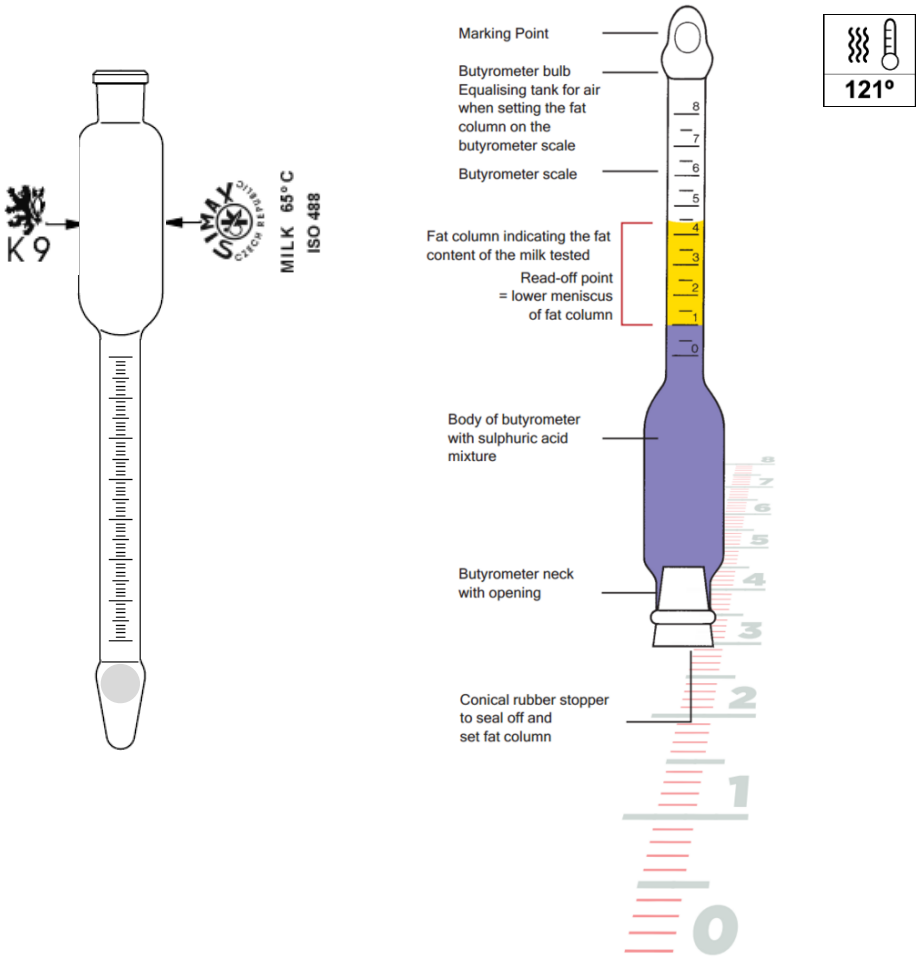
Issuer´s name/ producer: **KAVALIERGLASS, a.s.**

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

Object of the declaration: **BUTYROMETER FOR MILK, acc. to GERBER**

Product IDN	Catalog Nr.
7330	1632438010600

Scheme of the glass item



Material specification:		
Butyrometer	clear	Borosilicate glass SIMAX®
Print on the body	red brown PANTONE 484C	in fired-on, chemically resistant ceramic enamel
Purpose of use	Suitable for laboratory analysis in dairy quality control Determination of fat content in milk using Gerber method	

Technical Specifications:

Fat content range [%]	0-6 %	
Overall length	190 ± 2,5	
Volume per 1% fat (20 °C) [ml]	0,125	
Scale volume [ml]	0,75	
Scale division	1:10	*Equivalent to 0,1% fat increments*
Maximum permissible error [µL]	± 3,75	

Thermal resistance	up to 100 °C	
Reusability	Chemically cleanable and autoclavable	121 °C/ 20 min/ 2,05 bar 134 °C/ 10 min/ 3,04 bar
Centrifuge compatibility	Gerber – type centrifuges	

Recommended reagents				
Sulfuric acid	90-91 %	density	1,820-1,825 g/ cm^3	Protein digestion, fat release
Amyl alcohol	≥ 98 % isoamyl alcohol			Prevents emulsion, aids fat separation
Distilled water - Impurity free		temperature 65 – 70 °C		Volume adjustment for reading

Note: Use appropriate PPE. Handle reagents in accordance with laboratory safety protocols.

Handling & Storage:

- Store in original packaging in a dry, dust-free environment
- Avoid mechanical shock and rapid temperature changes
- Do not use damaged, chipped or cracked glassware

Legal Metrology Compliance:

- This butyrometer is subject to metrological control under Czech national regulation.
- Verified according to **Instruction I-1311** issued by the Czech Metrology Institute (ČMI).
- Verification is performed and the butyrometer is appropriately marked; no individual verification certificate is issued to the customer.

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)

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

- ISO 19662:2018 Acido-butyrometric (Gerber method)

- For butyrometers beyond the scope of ISO 19662 (e.g. 0–7 %, 0–8 %, skimmed milk variants):
  ISO 488:2008 (withdrawn) is used as a technical reference.
  All tolerances and specifications remain consistent with ISO 488.

Regulatory Note
This product conforms to ISO 19662:2018. For butyrometers not covered by this standard, ISO 488:2008 remains a valid engineering reference. All dimensional and accuracy requirements comply with historical metrological norms.

- Glass containers for pharmaceutical use
  - Eur. Ph 10th Edition -3.2.1 Glass Type I.

- Regulation (EC) No. 1935/2004 of 27th October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

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)*
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.**

Sázava, 15. 07. 2025
Place and date of issue

Ing. Kristýna Machová
Project Quality Engineer

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