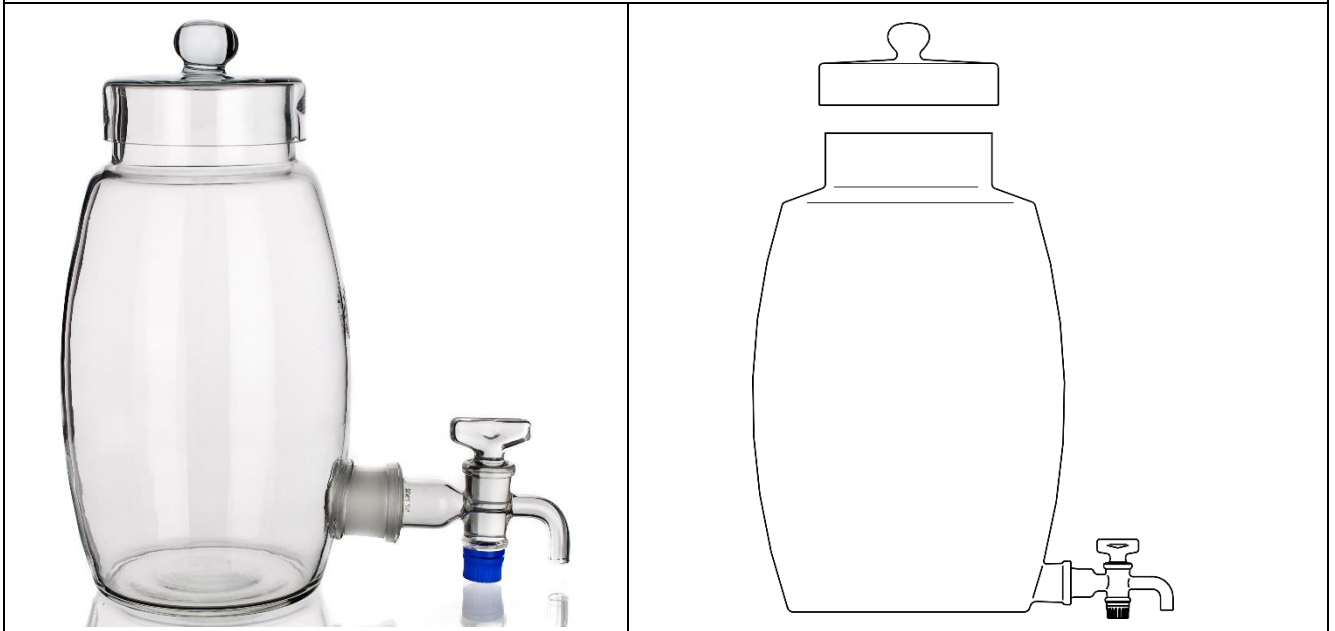


Issuer's name/ producer: **KAVALIERGLASS, a.s.**
Issuer's address/Producer: **Křížová 1018/6, Prague 5**
office: Sklářská 359, 285 06 Sázava, Czech Republic

Object of the declaration: **IRRIGATOR, barrel shaped,
 tubulated near bottom**

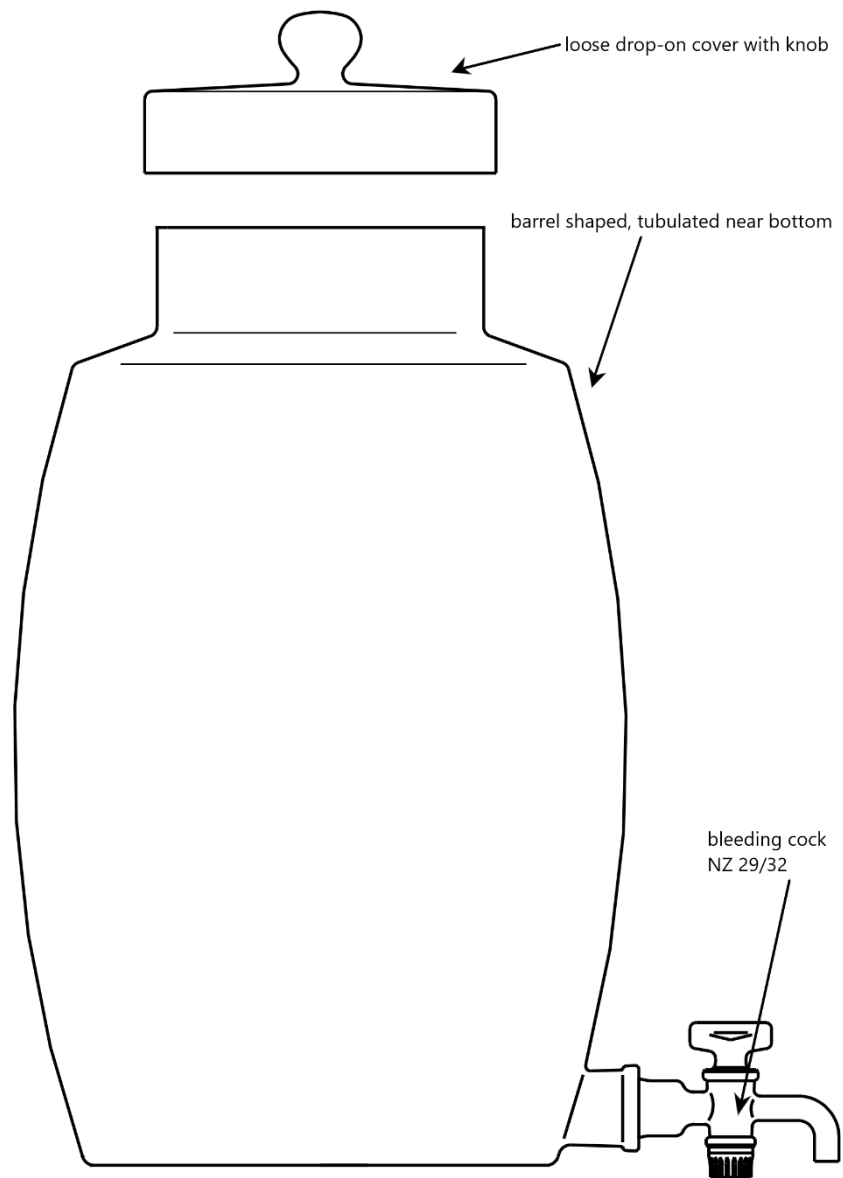
<u>Product IDN & Description</u>	<u>Catalog Nr.</u>	<u>Capacity/ ml</u>	<u>Plug No. /NZ</u>
827R clear bottles	1632415623966	10000	No. 6/NZ 29/32

Glass bottle and Plastic accessories



Material specification:		
Bottle body	clear	Borosilicate glass SIMAX®
Plug No. 6; NZ 29/32	blue	PP - MOSTEN MA 230
O-ring	black	NBR70
Purpose of use	dosage of liquids, medical purposes	

Detailed scheme of individual parts of the Teflon stopcock



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

Technical standards for products:

- ISO 4796 Laboratory glassware, bottles

No heavy metals (lead, cadmium, mercury and hexavalent chromium):

- RoHS

Directive 2011/65/EU of the European parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

- **RoHS III Directive**

PTFE stopcock The products PTFE based materials currently supplied by Guarniflon SpA do not contain the following substances (Lead, Mercury, Hexavalent Chromium, Cadmium, PBB, PBDE, DEHP, BBP, DBP, DIBP)

- **Commission Regulation (EU) No. 2023/2006**

Glass Good manufacturing practice for materials and articles intended to come into contact with food

- **Regulation EC No 1935/2004 of 27 October 2004**

Glass 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.**

Glass 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 7086-1:2000 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

- **BS EN 1388-2:1996**

Materials and articles in contact with foodstuffs. Silicate surfaces. Determination of the release of lead and cadmium from silicate surfaces other than ceramic ware.

- **Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December - [EU REACH Regulation](#)**

Products do not release Substances of Very High Concern (SVHCs) above their respective threshold values listed in SVHC-Candidate List, as of the date of inclusion: 08 July 2021 as part of their formulation.

Please refer to ECHA website below for the detail of SVHC. <https://echa.europa.eu/candidate-list-table>

- **Decree 306/2012 Coll. on conditions for the prevention and spread of infectious diseases, and hygienic requirements for the operation of medical facilities and social care institutions**

Relating the specific conditions for sterilization

- **California's Safe Drinking Water & Toxic Enforcement act of 1986 (Proposition 65)**

Glass Products do not contain chemicals, which are listed on (Prop 65)

Plug No. 6; NZ 29/32

Products do not contain chemicals, which are listed on (Prop 65)

The Current Proposition 65 list can be found at: <https://oehha.ca.gov/proposition-65/proposition-65-list>

Technical requirements according to purpose of use

Characteristics of Borosilicate glass SIMAX®

- **Acid resistance** Class I. (to ISO 1776)
- **Hydrolytic resistance** Class I. (HGB1 to ISO 719; HGA1 to ISO 720)
- **Alkali resistance** Class II. (to ISO 695)
- **Coefficient of mean linear thermal expansion α : $3,3 \times 10^{-6} \text{ K}^{-1}$ (to ISO 7991; 20/300 °C)**
- **Pharmaceutical use**

	<i>European Pharmacopoeia (EP)</i>	<i>US Pharmacopoeia (USP)</i>	<i>Japanese Pharmacopoeia (JP)</i>
Glass	Eur. Ph.10.Edition – 3.2.1	USP <660>	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	$\mu\text{g As/g}$	max 0,1	< 0,001

Plug No. 6; NZ 29/32 Eur. Ph.9 – 3.1.3; based on the statement of the supplier

- **Temperature resistance**

Glass The maximum permissible short-term operating temperature is 500°C
The maximum thermal shock resistance is $\Delta T=100 \text{ K}$.

Plug No. 6; NZ 29/32 -40°C to +140°C

- **Sterilization***

Hot air sterilization, in the oven	up to 140°C
Steam sterilization, in an autoclave	121°C/ 20 min 134°C/ 10 min

* The bottle can be sterilized.

During sterilization, the cock can only lightly be fitted on the bottle (screw max. one rotation). Pressures are not equalized when the bottle is closed. The pressure difference created in this way can result in the bottle breakage. The bottles can be hot-air sterilized up to 140°C, or autoclaved up to 121°C, or 134°C.

Additional information:

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 to such products. Certificate No. 44 100 940602 issued by TÜV CERT, Certification Body at TÜV NORD CERT GmbH.

The certificate is issued for the customer: **AUXILAB S.L.**

Sázava, 02. 12. 2021
Place and date of issue

Ing. Kristýna Machová
Project Quality Engineer

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