

Name:	Stackable Cuvette, 1 mL
Purpose:	Reaction vessel for liquids single use
Ident No.:	Stackable Cuvette, 1 mL – Ident No.:10033666
Packaging units:	Stackable Cuvette, 1 mL, Set of 3000 pieces
Material:	PP medical grade
BASIC UDI-DI:	91201239110010DZ

1 INTENDED USE

The intended use is as a reaction vessel for liquids.

They are intended exclusively for single use only and for application by qualified staff.

The cuvette is designed to be used for automated analytical systems, e.g. KleeYa System in line with *in vitro* diagnostic analyses.

INFO

The Stackable Cuvettes are validated for use in combination with the KleeYa instrument. In their function of KleeYa accessories, they are classified as Class A IVD medical devices in regards to EU IVD regulation 2017/746. Conformity with the relevant General Safety and Performance Requirements is demonstrated for the Anchor Tips in connection with the KleeYa instrument.

For more information about the Stackable Cuvette 1mL please refer to the KleeYa User Manual.

⚠ WARNING



Handling

This instruction is provided for your safety and gives important instructions for the handling of the article.

- Read all instructions (including KleeYa User Manual)!
- Do not use damaged articles!
- Do not use any articles whose direct packaging is damaged!
- Do not use any articles whose expiration date has been exceeded!
- Never reuse single-use articles! Repeatedly use of single-use articles might cause cross-contamination. Furthermore, correct product performance is not guaranteed anymore.

2 SPECIFICATIONS

Nominal volume:	1 mL
Processing volume:	600 µL
Residual volume:	≤ 10 µL

3 USE

Stackable Cuvettes are loaded stack-wise into the KleeYa System. Through an opening in the top cover the system is fed with cuvettes. Stackable Cuvettes can be loaded during the run. The KleeYa System has the capability to host of up to 500 cuvettes.

For further instructions for use see KleeYa User Manual “3.3.2 Load Cuvettes”.

4 ENVIRONMENTAL CONDITIONS

	Temperature	Operating: 2°C to 37°C + 3°C (35,6°F to 98,6°F + 5,4°F)
		Storage: 2°C to 32°C (35,6°F to 89,6°F) for a maximum of 3 years
		Transport: -10°C to 60°C (14°F to 140°F) for a maximum of 3 days
	Humidity	Operating: 20 – 80 % non-condensing
		Storage: 20 - 80 % non-condensing for a maximum of 3 years
		Transport: 10 - 90 % non-condensing for a maximum of 3 days
NOTICE		Protect from sunlight and UV rays!

5 DISPOSAL AND DECONTAMINATION

NOTICE**Disposal of non-contaminated parts**

Material out of use (e.g. packaging material, units with damaged direct packaging) should be properly disposed according to local waste disposal regulations.

⚠ WARNING**Disposal of contaminated parts**

Potential infectious material will cause severe environmental contamination.

Strictly follow the local and national provisions, legislation and laboratory regulations.

6 SUPPORT

NOTICE

E-mail: Support.KleeYa@diatron.com

7 MANUFACTURER

Manufactured in Germany for STRATEC Consumables GmbH.



STRATEC Consumables GmbH

Sonystrasse 20

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Austria

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