# ZERTIFIKAT
# CERTIFICATE

Pumpen | Probenehmer | Laborbedarf
für Labor, Industrie und Wissenschaft

Pumps | Sampling | Plastic Labware
for Laboratory, Industry, Science

5393-8000 PharmaDispo disposable powder sampler, 0.01ml
5393-8001 PharmaDispo disposable sampler, sterile, 0.01ml
5393-8010 PharmaDispo disposable powder sampler, 0.05ml
5393-8011 PharmaDispo disposable sampler, sterile, 0.05ml
5393-8020 PharmaDispo disposable powder sampler, 0.1ml
5393-8021 PharmaDispo disposable sampler, sterile, 0.1ml
5393-8030 PharmaDispo disposable powder sampler, 0.5ml
5393-8031 PharmaDispo disposable sampler, sterile, 0.5ml
5393-8040 PharmaDispo disposable powder sampler, 1.0ml
5393-8041 PharmaDispo disposable sampler, sterile, 1.0ml

## Declaration of Compliance

Food regulatory assessment - European Union

Compliance with General Food Contact Legislation

Bürkle GmbH confirms that the products listed above are in compliance with the applicable requirements of the Regulation (EU) No. 1935/2004 and Regulation (EU) No. 10/2011.

We hereby declare that, in the manufacture of the products, it follows the good manufacturing practice requirements according to (EC) No. 2023/2006.

OML - overall migration limits

- 3 % acetic acid: 0.6 mg / $dm^2$ (specification limit: 10 mg / $dm^2$)
- 50 % ethanol: 0.1 mg / $dm^2$ (specification limit: 10 mg / $dm^2$)
- Tenax: 0.4 mg / dm2 (specification limit: 10 mg / dm2)

As the alternative fat simulants 95 % ethanol and isooctane affect polystyrene too strongly, the overall migration was determined into 50 % ethanol in accordance with the FDA Chemistry Recommendations for Food Contact Notifications (April 2002).

The investigated samples are in compliance with the overall migration limit **for all types of food at long term storage at room temperature and below, including hot fill (e.g. 2 h / 70 °C or 15 min / 100 °C).**

Conformity has been established by:
Determination of total migration (contact area/volume: 1.0 $dm^2$ / 100 ml. The analyses were carried out on a representative sample (unirradiated) and are transferable to all other above listed 5378 series samplers.

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SML - specific migration limit

The limit for specific migration of zinc is 5 mg/kg, of aluminum 1 mg/kg, of n-octylphosphonic acid 0.05 mg/kg (50 µg/kg) and of tetrakis(2,4-di-tert-butylphenyl)-4,4'biphenylene-diphosphonite (Ref 92560) 18 mg/kg food (simulant) according to the European Plastics Regulation (EU) No. 10/2011 (last amended by Regulation (EU) No. 2020/1245).
The tested articles comply with the limits for specific migration of the above substances in contact with **all types of food for any long-term contact at room temperature or below, including short-term hot contact, e.g. 15 min / 100 °C or 2 h / 70 °C.**

Conformity has been established by:
Determination of the specific migration of additives (contact area/volume: 1 $dm^2$ / 100 ml). The analyses were carried out on a representative sample (unirradiated) and are transferable to all other above listed 5378 series samplers.

No dual use substances are used.

The information on dual use substances is provided by our raw material supplier. It seems very unlikely that a food additive used as a plastic additive will compromise the compliance with the regulatory threshold for this additive in the food product.

**A functional barrier made from plastic is not used in the above mentioned products.**

The user has to convince himself of the suitability of the product for the intended filling material which goes beyond the requirements of the directives.

The declaration is based on our current state of knowledge and information provided by our supplier at the time that the document was drawn up. The supplier – Bürkle GmbH in Bad Bellingen/Germany – is certified according to the standard DIN EN ISO 9001 by the DQS (German Society for Quality Assurance) since 1995. The number of certificate is 002284-QM15.

20. September 2024

Bürkle GmbH, Bad Bellingen,
Martin Saint-Denis, Managing Director