ZERTIFIKAT
CERTIFICATE

Pumpen | Probenehmer | Laborbedarf
für Labor, Industrie und Wissenschaft

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

5344-xxxx SteriBag

The above named articles comply to the migration criteria defined in the Food and Drug Administration (21 CFR 177.1520 (c)3.1a, (c)3.2a and 178.2010) regulations and the European Union No 10/2011 regulation.

HEAVY METALS : No antimony, arsenic, barium, cadmium, chromium, lead, nickel, selenium, silver, zinc or mercury, among others, is used in the formulation of the products. No heavy metal is intentionally introduced into the material's formulation and does not exceed 100 ppm in compliance with CONEG and RoHS model requirements.

ANIMAL DERIVATIVES AND GMO: the products are formulated without any tallow-based derivative material and therefore comply with USDA regulations for exposure to transmissible spongiform encephalopathy (TSE) / bovine spongiform encephalopathy (BSE). Product is GMO free.

LATEX, RUBBER, PHTHALATES : Product is free of any rubber or latex components and no phthalates are intentionally added or used as additives or raw material in the manufacture of this product.

ADDITIVES: No bisphenol A, antimicrobial, fungicidal, pesticidal or similar additives is used as additive or raw material in the manufacture of this product. Product is free of melamine and melamine was not intentionally added or used as an additive or raw material in the manufacture of this product.

RNASE / DNASE / PYROGENS : Product is RNase/DNase and pyrogen free.

The above named articles are made of low density virgin polyethylene (LDPE) manufactured in accordance with FDA (Food and Drug Administration) specifications.

Tube is extruded and biologically inert. Product has a 5-year sterility warranty.

Product should not be used at temperatures greater than 80°C (176°F) or temperatures lower than -100°C (-148°F), as advised by raw material suppliers. In any case, it is strongly recommended to only use products for transportation or sampling. Product is not meant to be used as packaging.

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Sterility is ensured by extrusion temperatures exceeding 220°C which will eliminate any present bacteria. Only once the bag is opened by tearing along the perforated line is the bag's interior susceptible to possible contamination from its present environment.

To further document this process, random lots are analyzed based on USP40-NF35 general chapter 71 Sterility Tests for:

1) Total aerobic bacteria detection
2) Total anaerobic bacteria detection
3) Yeast detection
4) Mould detection

Cleanroom bags (5344-80xx), with their external pouches, are further sterilized by gamma irradiation. To confirm the efficiency of our processes, validation tests are performed based on ISO 11137-1 and 11137-2 standards.

These products have been validated to have a Sterility assurance level of 10^{-3}.

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 2284-08.

06. March 2023

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