

5344-0xxx Sampling bag SteriBag, w/lab.area / w/o lab.area

Dear Sir or Madam,

With the entry into force of Regulation (EU) 2025/40 on packaging and packaging waste (Packaging and Packaging Waste Regulation – PPWR), new requirements for packaging are being introduced across Europe.

This statement covers both the products listed above and the associated transport packaging used by Bürkle to supply these products.

Bürkle GmbH continuously monitors the implementation of the PPWR and assesses its impact on our packaging portfolio and the products we place on the market.

As part of our role as a manufacturer, importer and distributor, we are providing our customers with the necessary information and are gradually compiling the technical documentation required by law in accordance with the transition periods set out in the Regulation.

Requirements already fulfilled

Heavy metals in accordance with Article 5 of the PPWR

We hereby confirm that the packaging and packaging components supplied by Bürkle GmbH comply with Article 5(4) of Regulation (EU) 2025/40.

The sum of the concentrations of

- lead
- cadmium
- mercury
- hexavalent chromium (Cr VI)

does not exceed the limit value of **100 mg/kg**.

PFAS in accordance with Article 5 of the PPWR *(relevant only to food-contact packaging)*

Based on the material information and supplier declarations available to us, the food-contact packaging used complies, to the best of our current knowledge, with the requirements of Article 5(5) of Regulation (EU) 2025/40 on packaging and packaging waste (PPWR).

This applies in particular to the limit values set out in the Regulation of

- 25 ppb for individual PFAS,
- 250 ppb for the total PFAS, and
- 50 ppm total fluorine (including polymeric PFAS),

insofar as these requirements apply to the packaging in question.

Requirements coming into force at a later date

The following requirements of the PPWR are coming into force in stages or are currently being further specified through delegated acts and harmonised standards. Bürkle GmbH continuously monitors these developments and adapts its technical documentation and packaging solutions accordingly.

Recyclability in accordance with Article 6 of the PPWR – Many of our packaging solutions are already designed with recyclability in mind. Future recyclability requirements will be assessed in accordance with the European guidelines yet to be published, as well as the assessment methods set out by the European Commission for this purpose.

Minimum recycled content requirements for plastic packaging in accordance with Article 7 of the PPWR – The requirements regarding minimum recycled content for certain types of plastic packaging will come into force in stages from 2030. The relevant calculation guidelines are currently being further refined at European level. As soon as these are available, we will provide the necessary evidence to the required extent.

These requirements do not apply to packaging or packaging components that do not contain any plastic or that fall under a statutory exemption pursuant to Article 7 of the PPWR.

Minimisation in accordance with Article 10 of the PPWR – We already optimise our packaging to minimise material usage. The packaging and packaging components we supply are designed to meet protection, transport and functional requirements, and are kept to the minimum necessary. We avoid unnecessary packaging components without compromising product safety or functionality.

Reuse in accordance with Article 11 of the PPWR – We assess the requirements for reusable packaging in accordance with the specific type of packaging and its intended use. Where Article 11 applies to a particular packaging type, these requirements are taken into account as part of the ongoing development of our packaging portfolio.

Labelling in accordance with Article 12 of the PPWR – The labelling requirements that will be mandatory in future will be implemented in accordance with the statutory transition periods.

The information is based on the current legal requirements and on the information available from our suppliers at the time of drafting.

As certain requirements of the PPWR are still being finalised, we reserve the right to update this document. Please do not hesitate to contact us if you have any queries. Email: info@buerkle.de

September 17, 2026



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