

5378-10xx scoop (w/o lid) / spatula / spoon / scraper / forceps, SteriPlast, white
5378-40xx dosing spoon, SteriPlast, white
5378-50xx scoop / spoon / ladle, SteriPlast, white
5378-60xx funnel PS, Ø100mm, white, sterile

Statement on endotoxins

Articles listed above are not regularly tested for endotoxins. However, endotoxines were tested on the three batches listed below:

Description	Lot	Concentration [EU / device]
scoop, single-use, PS, 25 ml	220490	<20
measuring spoons 15 ml, PS, blue	220932	<20
sterile scoop, single-use, PS, 50 ml	221103	<20

Manufacturing of routine articles is comparable to manufacturing of articles mentioned above in every aspect: manufacturing conditions, manufacturing equipment, raw materials, and packaging materials. Microbiological burden of articles as well as radiation dose of routine articles are verified according to ISO 11137 on a regular basis.

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.

01. September 2022



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

