

## 5325-0xx0 SteriPlast Syringe

### Material

COMPONENT	MATERIAL
Barrels	POLYPROPYLENE
Plunger rods	POLYPROPYLENE
Barrel cat# 309628	POLYCARBONATE
Stoppers	LATEX FREE ELASTOMER
Lubricant	MEDICAL GRADE SILICONE OIL, <0.25 mg/cm <sup>2</sup>

### Material of concern

Materials of concern are chemicals or substances that have been identified as having the potential to cause long term effects on humans or the environment.

MATERIAL	COMMENT
Phthalates	The products do not contain phthalates. No DEHP, CAS number 117-81-1, EC number 204-211-0, intentionally added
Latex	The products do not contain natural latex.
Bisphenol A	The products do not contain Bisphenol A.
Substances of animal origin BSE/TSE	The raw material used in manufacture of this medical device do not contain any animal tissue but may contain very small amounts of animal-derived raw materials. This product is manufactured using polymers resins which may contain very small amounts of surfactants or fatty acids derived from tallow. Our resin suppliers have confirmed that these tallow-derived have been produced with multiple cycles of conditions at least as rigorous as those specified in Annex C.5 of EN 22442-1 and section 6 of EMA 410/01. Therefore, these raw materials meet or exceed the requirements of EN 22442-1 and EMA 410/01. Based on this information, this product is considered not to present any risk with respect to TSE/BSE or other animal-borne diseases Furthermore, as recognized by MEDDEV 2.4/1, tallow processed in accordance with the aforementioned standards and guidelines is considered irrelevant when determining the classification of a medical device (per MDD 93/42/EEC). These devices utilize very small amounts of tallow or tallow derivatives (e.g. stearates in polymers). Per MEDDEV 2.4/1 Rev. 9 June 2010 and the Directive 2003/32/CE, such substances are not considered as derivatives of animal tissues for the purpose of this rule which therefore does not apply.
Polyvinyl chloride (PVC)	The products do not contain polyvinyl chloride

### REACH information

Our supplier maintains an active REACH compliance program and works closely with its supply base on an ongoing basis with a view to obtaining information on REACH Substances of Very High Concern ("SVHC") through regular communication and exchange

### Biocompatibility

Our supplier Medical products comply with the requirements of the standard for biocompatibility of medical devices, ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

### Shelf life

Shelf life 5 years.

No special storage or transportation condition. Recommendations are to store in room temperature, in dry and warm place and not exposed to strong light.

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.

May 2017

A handwritten signature in blue ink, appearing to read "M. Saint-Denis".

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

