

**Corning Incorporated
Life Sciences**

**Registered
ISO 9001:2008**

Product Description

Catalog Number: 3546

Product Description: Corning ® Spinner Flask, Disposable, 1L, w/Aseptic Transfer Cap, MPC

Component Materials:

- Vessel - Virgin Polystyrene, *meets USP, Class VI* requirements for plastic containers and closures, "complies with International Organization for Standardization (ISO) 10993-18, Biological Evaluation of Medical Devices - Part 18: Chemical Characterization of Materials (2005)."
- Impeller - Polypropylene, *meets USP, Class VI* requirements for plastic containers and closures, "complies with International Organization for Standardization (ISO) 10993-18, Biological Evaluation of Medical Devices - Part 18: Chemical Characterization of Materials (2005)."
- Caps - High Density Polyethylene, *meets USP, Class VI* requirements for plastic containers and closures.
- Magnet Tubing - Polytetrafluoroethylene encapsulated ALNICO magnet, 12800 Gauss induction
- Tubing - C-Flex thermoplastic elastomer, *meets USP, Class VI* requirements for plastic containers and closures
- Filter - 0.2µm ePTFE membrane, *meets USP, Class VI* requirements for plastic containers and closures
- MPC Quick Connect - Medical Grade PC, *meets USP, Class VI* requirements.

Product Dimensions:

Height of Vessel	- 9.64 in. (24.48cm)	Diameter of Vessel	- 8.0 in. (20.32cm)
Sidearm Opening of Vessel	- 1.53 in (3.88cm)	Sidearm Cap of Vessel	- 45 mm GL 45
Cap Diameter	- 1.77 in (4.49cm)	Cap Height	- 1.0 in (2.54cm)
Working Volume	- 1L maximum	Tolerances	- +/- 0.05

Sterilization:

The product is irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 (AAMI TIR 33) *Sterilization of healthcare products-Requirements for validation and routine control-Radiation sterilization.*

Sterility Assurance Level: SAL 10⁻⁶

Pyrogens:

This vessel has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72:2002/(R)2010 *Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing.*
Results: ≤ 0.1 EU/mL (≤ 4EU/device)

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product is manufactured and packaged with animal free materials.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Visual Attributes:

Visual examination of the product.

Packaging:

Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.

Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacturing; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.

Rev No: 4