Corning Incorporated
Life Sciences

Registered
ISO 9001:2008

Product Description

Catalog Number: 3559

Product Description: Corning ® Spinner Flask, Disposable, 3L, 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	-	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	-	10.20 in. (25.91cm)	Diameter of Vessel	-	10.08 in (25.63cm)
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	-	3L 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}

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:
This product is manufactured and packaged with animal free materials.

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)

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