

Certificate of Compliance

Description: 80mL-190mL Cryo Bag
Catalog #: 91-200-91
Lot #: 705504
Expiration Date: 04-2023
Irradiation Date: 04-2021
Storage -20 to 40°C
Country of Manufacture: USA

Notes:

This is to certify that this product has been manufactured in a manner compliant with current Good Manufacturing Practices (cGMPs), FDA regulation 21 CFR part 820 and ISO 13485 Quality Standard.

The fluid pathways are classified USP VI and/or ISO-10993. The fluid path raw materials conform to the European guidance EMA/410/01 and the U.S. CFR Title 9 of Part 94.18

For research and manufacturing uses. Not for human therapeutic use. Utilization of this product apart from the labeled intended use may be a violation of local and/or Federal Law.

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

Visual Attributes: Visual examination of the product.

Packaging: Inspection for packaging integrity, accurate labeling, and correct product configuration.

Biological Reactivity: All product contact materials have passed USP Class VI testing (USP <88>) and / or ISO 10993.

Gamma Irradiation: Fully assembled Cryogenic Containers are gamma irradiated. Dosimeter measurement confirms all portions of the packing environment received 25-50 kGy.

Endotoxin: Samples of finished containers were tested for the presence of endotoxin (per the USP Bacterial Endotoxin Test). Aqueous extracts contained <= 20 EU/device as determined by the Limulus Amebocyte Lysate Test (LAL).

For further information, contact Corning Scientific Support at 800-492-1110 or ScientificSupport@corning.com

Following signatures indicate the above material has met all quality specifications and has been reviewed by a Quality representative.

Written By/Date: [Signature] 30 Mar 2022

Reviewed By/Date: [Signature] 30 Mar 2022



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