Certificate of Compliance

Corning Incorporated - Life Sciences
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Refer to website for regional contact information.

Product Name	:	CellSTACK Chamber,1 STACK,POLYSTRYENE,STERILE,1/8 Notes		
Catalog Number	:	3268	**Manufacture Date**	: 2022-03-14
Lot ID	:	07322048		
Expiration Date	:	2025-03-13		

Quality Management System - Complies with the current version of the ISO 9001 Standard and the FDA CFR 21 Part 820, current Good Manufacturing Practices (cGMP).

Animal Content - Product does not contain materials of animal origin.

Non-Pyrogenic - Vessel tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing" and USP <85>, "Bacterial Endotoxins Test". The acceptance level for product is ≤ 0.10 EU/mL or ≤ 4 EU/device.

USP Class VI Testing - All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological reactivity Tests, in Vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

Sterilization - Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, "Sterilization of health care products - Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10^{-6}.

Sterility - Products labeled Sterile Fluid Path have been designed to ensure sterility of the portion of the product intended for contact with fluids.

Tissue Culture - Tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line. A minimum of 95% confluency is required for acceptance.

Quality Control Testing - Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

- Visual Inspection - Pass
- Packaging Inspection - Pass
- Cell Attachment & Growth Treatment Verification - Pass
- Leak Test - Pass

- This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release.

Olga I Stridiron Monell
Plant Quality Manager

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