CORNING

Certificate of Compliance

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

Product Name	:	FLTR SYS,1000ML,.2UM,NY,S,IND		
Catalog Number	:	430515	**Manufacture Date**	: 2022-02-01
Lot ID	:	03222001		
Expiration Date	:	2025-02-01		

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).

BSE/TSE - Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

Non-Pyrogenic - 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".

Sterility - 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^{-5}.

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

Product Specification Standards - Tested to ASTM Standard F838, "Standard Test Method for Determining Bacterial Retention of Membrane Filters Utilized for Liquid Filtration". Sterile filtrate produced per standard.

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
- Membrane Integrity Test - Pass

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

David P. Kieru

DAVID P (DAVE) KIERU
Quality Manager