

## **Certificate of Compliance**

Corning Incorporated - Life Sciences 275 River Street Oneonta NY 13820 USA www.corning.com/lifesciences Refer to website for regional contact information.

Page: 1 / 1

Product Name	:	SPIN-X UF, 20mL CONCENTRATOR, 10K CUTOFF, NS, IND, 1/12
Catalog Number	:	431488 Manufacture Date : 2022-03-28
Lot ID	:	08722005
Expiration Date	:	2024-03-28

**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).

**Membrane Recovery Efficiency** - Tested at 4,000 xg, using a molecular weight marker of appropriate cutoff for the level of concentrator. Acceptance is a minimum recovery of 20% filtrate.

**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 Integrity Test - Pass

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

Dania P. Klenu

DAVID P (DAVE) KIERU Quality Manager