

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

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Product Name	: SPINX FLTR, 2ML, .22UM, CA, NS, BK		
Catalog Number	: 8161	Manufacture Date	: 2023-05-18
Lot ID	: 13823000		
Expiration Date	: 2026-05-18		

Quality Management System - Complies with the current version of the EN ISO 13485 Standard.

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.

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". Assembled device has been tested, qualified, and shown to be non-toxic as established in the Standard USP Class VI Chapter <87>, "Biological Reactivity Tests, in Vitro".

DNase/RNase Free - Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-5} Kunitz units/ul for DNase and 10^{-9} Kunitz units/ul for RNase.

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

Human DNA Free - Tested by PCR method and found to be free of detectable human DNA contamination. The assay detection limit is hDNA 5pg.

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



Anthony Sloan
Quality Manager