

Certificate of Compliance

Product Description

ASI's Product No: B100363-I
 Rev: A
 Customer Product No: 89127-022
 Lot Number: 97S4X-0000
 Irradiation Dosage Range: 25 kGy - 45 kGy
 Irradiation Date: June 2018
 Irradiation Run No: 2215162
 Description: 200 Liter Tank Liner

Manufactured Date: May 2018
 Expiration Date: May 2021
 Purchase Order No: 4508438159
 Quantity Shipped: 20

Specifications:

STATEMENTS:

Biological Reactivity Tests in-vitro and in-vivo:	The fluid path of Advanced Scientifics' single use systems are classified USP Class VI and/or ISO-10993.
Physiochemical Test:	Fluid contact film of Advanced Scientifics' bags have passed current USP <661> tests for plastic containers.
TSE-BSE Status:	The fluid path raw materials conform to the European guidance EMA/410/01 and the U.S. CFR Title 9 of Part 94.18.

MONITORING:

Endotoxin:	The fluid path of representative Finished Product has been sampled and tested according to current USP <85> Bacterial Endotoxins test by LAL. Passes the FDA acceptance criteria of ≤ 0.5 EU/ml.
Bioburden:	The fluid path of representative Finished Product has been sampled and tested according to ISO 11737 method by filtration. Passes the acceptance limits determined by validation.
Sterility:	The Finished Product's fluid path has been validated according to AAMI TIR33 with a 10^{-6} Sterility Assurance Level (SAL).

BATCH TESTING:

Visual Inspection:	100% of the products are inspected and pass Advanced Scientifics specification.
Product Conformity:	Technical drawing compliance and batch record reviewed.
Gamma Irradiation:	The Gamma Irradiation Certificate from the approved contractor is enclosed.

Advanced Scientifics, Inc. certifies the product supplied has been manufactured under Current Good Manufacturing Practices and the following:

- FDA Regulations 21 CFR Part 820
- ISO 13485:2003 Quality Standards

The product listed above has been inspected and tested in accordance with the applicable specifications and drawing requirements. Further information on this product may be obtained by contacting Customer Service at Advanced Scientifics, Inc.



John Briggs - Director of Quality, Regulatory and Compliance

6/8/2018

Date of Release