



Certificate of Conformance and Sterility

This certification is provided as full assurance that the following product code and lot number were manufactured in accordance via a Quality System certified to ISO 9001 with prescribed procedures and specifications.

Product Code:	LVK-MOPIR
Lot Number:	1043345-0-0-1
Manufacturing Date:	01/12/2024
Expiration Date:	01/2026

Sterility

Gamma Processing Run ID:	1153-9469A
Irradiation Dose Specified:	30.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	33.5 kGy to 48.0 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)

A handwritten signature in black ink, appearing to read "C. Duffee".

QC Supervisor
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Thursday, January 18, 2024

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DID: 1821B

STERIS: Gamma Certificate Of Processing

Prepared for: CONTEC INC (1963)
Gamma Process Run ID 1153-9469A

Product Code	Lot Number	Quantity	UOM
LVK-MOP-IR	1043342-0-0-1	36	Case
LVK-MOP-IR	1043343-0-0-1	36	Case
LVK-MOP-IR	1043344-0-0-1	36	Case
LVK-MOP-IR	1043345-0-0-1	36	Case
MVK-MOP-IR	1035779-0-0-1	18	Case
MVK-MOP-IR	1035783-0-0-1	18	Case
MVK-MOP-IR	1035784-0-0-1	18	Case
TLVKMOPIR	1042851-0-0-1	18	Case
TLVKMOPIR	1042852-0-0-1	18	Case
HCKM3053	1042866-0-0-1	24	Case
HCKM3053	1042867-0-0-1	24	Case
VKMX0375	1035818-0-0-1	24	Case
VKSE0150	1044166-0-0-1	27	Case
VKSE0250	1042759-0-0-1	24	Case
VKSE0250	1042760-0-0-1	24	Case
VKSE0250	1042761-0-0-1	24	Case
VKSE0250	1042762-0-0-1	24	Case
VKSE0350	1042948-0-0-1	30	Case
VKSE0350	1042949-0-0-1	30	Case
VKSE0350	1042954-0-0-1	30	Case
VKST0003	1039706-0-0-1	18	Case
VKST0003	1043048-0-0-1	18	Case

Processing Run Start Date: 16-Jan-2024 11:39 PM

Processing Run End Date: 17-Jan-2024 1:24 PM

Minimum Specified Dose (kGy):	30.0	Minimum Delivered Dose (kGy):	33.5
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	48.0

Product meets Customer specifications; zero nonconformities occurred during this irradiation run.

Signature Manifest

Reviewed and E-Signed By: Pachy Thor (Quality Analyst)

Date/Time E-Signed: 18-Jan-2024 6:16 AM

Document Content Revision: 1

Product Code**Lot Number****Quantity UOM**

provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485:2016, and in alignment with EN ANSI/AAMI/ISO 11137-1:2015.

Processing Location

2072 Southport Road
Spartanburg, SC 29306
United States of America
Phone: 864-582-3041