



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:	690491-0-0-1
Manufacturing Date:	04/18/2019
Expiration Date:	04/2021

Sterility

Gamma Processing Run ID:	55100A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	33.5 kGy to 47.2 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)

QC Supervisor
coc@contecinc.com

Wednesday, May 01, 2019

NORTH AMERICA

Contec, Inc.
525 Locust Grove
Spartanburg, SC 29303 USA
tel: +1 864 503 8333
fax: +1 864 503 8444

EUROPE

Contec, Inc.
ZI du Prat - R.P. 3707
F-56037 VANNES Cedex France
tel: +33 (0)2 97 43 76 98
fax: +33 (0) 97 43 76 86

ASIA

Contec Cleanroom Technology (Suzhou) Co., Ltd.
17 Longyun Road
Suzhou Industrial Park, Suzhou 215024 China
tel: +86 512 6274 4050
fax: +86 512 6274 4051

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web: www.contecinc.com
e-mail: info@contecinc.com

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 55100A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
LVK-MOP-IR	690491-0-0-1	18	CS
LVK-MOP-IR	690492-0-0-1	18	CS
LVK-MOP-IR	690493-0-0-1	18	CS
LVK-MOP-IR	690494-0-0-1	18	CS
LVK-MOP-IR	690495-0-0-1	18	CS
LVK-MOP-IR	692559-0-0-1	18	CS
LVK-MOP-IR	699939-0-0-1	18	CS
MVK-MOP-IR	682026-0-0-1	18	CS
MVK-MOP-IR	690508-0-0-1	18	CS
MVK-MOP-IR	690509-0-0-1	18	CS
MVK-MOP-IR	690510-0-0-1	18	CS
MVK-MOP-IR	690511-0-0-1	18	CS
MVK-MOP-IR	699936-0-0-1	18	CS

Processing Run Start Date/Time: 26-Apr-2019 11:52:33 pm Approx. Downtime (hours): 0.40
Processing Run End Date/Time: 27-Apr-2019 07:38:19 am

Minimum Specified Dose (kGy):	30.0	Minimum Delivered Dose (kGy):	33.5
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	47.2

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

Signature Manifest

Reviewed and E-Signed By



Danny Vassey (QS & RC Technician I)

Document Content Revision: 1

Signed On 4/28/2019 at 11:47 AM

UTC / GMT Offset (hh:mm): -4:00

Processing Location:

STERIS

2072 Southport Road
Spartanburg, SC 29306
Phone: 864-582-3041
Fax: 864-582-4075

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and provide services under a quality system which meets the requirements of FDA QSR, EN/ISO 13485, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137 or EN ANSI/AAMI/ISO 11135. For items processed with gamma irradiation, STERIS certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.