



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:	737867-0-0-1
Manufacturing Date:	11/06/2019
Expiration Date:	11/2021

Sterility

Gamma Processing Run ID:	56544A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	31.7 kGy to 45.3 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
coc@contecinc.com

Wednesday, November 13, 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

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

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DID: 1821B

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 56544A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
LVK-MOP-IR	737863-0-0-1	18	CS
LVK-MOP-IR	737864-0-0-1	18	CS
LVK-MOP-IR	737866-0-0-1	18	CS
LVK-MOP-IR	737867-0-0-1	18	CS
VKSE0250	736369-0-0-1	24	CS
VKSE0250	736370-0-0-1	24	CS
VKSE0250	736371-0-0-1	24	CS
VKSE0250	736372-0-0-1	24	CS
VKSE0250	736373-0-0-1	24	CS
VKSE0250	736374-0-0-1	24	CS
VKSE0250	736375-0-0-1	24	CS
VKSE0250	736376-0-0-1	24	CS
VKSE0250	736377-0-0-1	24	CS
VKSE0250	736379-0-0-1	24	CS
VKSE0250	736380-0-0-1	24	CS
VKSE0250	736381-0-0-1	24	CS
VKSE0250	736382-0-0-1	24	CS

Processing Run Start Date/Time: 10-Nov-2019 01:29:52 pm

Approx. Downtime (hours): 1.20

Processing Run End Date/Time: 10-Nov-2019 11:58:23 pm

Minimum Specified Dose (kGy):	30.0	Minimum Delivered Dose (kGy):	31.7
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	45.3

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

Signature Manifest

Reviewed and E-Signed By



Brandie McCurry (QS/RC Technician)

Document Content Revision: 1

Signed On 11/11/2019 at 2:05 PM

UTC / GMT Offset (hh:mm): -5:00

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.

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 56544A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
VKSE0250	736383-0-0-1	24	CS
VKSE0250	736384-0-0-1	24	CS
VKSE0250	736385-0-0-1	24	CS
VKSE0250	736386-0-0-1	24	CS
VKSE0250	736387-0-0-1	24	CS

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