

525 Locust Grove Spartanburg, SC 29303 864-503-8333 1-800-289-5762 fax 864-503-8444 www.contecinc.com

Date: August 11, 2015

CERTIFICATE OF CONFORMANCE AND STERILITY

This certification is provided as full assurance that the following product code and lot number was manufactured in accordance with prescribed procedures and specifications.

Product Code: MEQT0002

Lot Number: 425248-*-*-1

Manufacturing Date: 08/03/2015

Run Number: 45862A

Irradiation Dose Specified: 25.0kGy to 50.0kGy Irradiation Dose Delivered: 31.2kGy to 45.8kGy

Validated Sterile Product: Validation Sterile packets available upon request.

Sterility Assurance Level: 10^-6 (SAL determined by test method

AAMI/ISO 11137)

Expiration Date: 08/2017

QC Supervisor

coc@contecinc.com

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID 45862A

Product Code	Product Lot Number	Quantity	<u>UOM</u>
33502-730	429439-*-*-1	24	CS
33502-730	429444-*-*-1	24	CS
492238-960	417744-*-*-1	18	CS
EL-MOP-IR	429366-*-*-1	18	CS
LWCS0027	424782-*-*-1	18	cs
MEQT0002	425248-"-"-1	72	CS
MVK-MOP-IR	416447-*-*-1	18	CS
MVK-MOP-IR	418746-*-*-1	18	CS
MVK-MOP-IR	418747-*-*-1	18	CS
PN-99IR	422751-*-*-1	26	CS
PN-99IR	422752-*-*-1	26	CS
SB32IR	421716-*-*-1	48	CS

Processing Run Start Date/Time:

09-Aug-2015 12:11:35 am

Approx. Downtime (hours):

1.30

Processing Run End Date/Time:

09-Aug-2015 11:26:09 am

Minimum Specified Dose (kGy):

25.0

Minimum Delivered Dose (kGy):

31.2

Maximum Specified Dose (kGy):

50.0

Maximum Delivered Dose (kGy):

45.8

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

Signature Manifest

Reviewed and E-Signed By Princess Shaw (QS/RC Technician)

Document Content Revision: 1

Signed On 8/10/2015 at 11:39 AM UTC / GMT Offset (hh:mm): -4:00

Processing Location: STERIS Isomedix Services 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 13485:2003/2012, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137:2006 or EN ANSI/AAMI/ISO 11135:2007. For Items processed with gamma irradiation. STERIS Isomedix certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.