

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

## CERTIFICATE OF CONFORMANCE AND STERILITY

Date: October 14, 2015 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: 436737-\*-\*-1 Manufacturing Date: 10/02/2015 Run Number: 46273A

Irradiation Dose Specified: 25.0kGy to 50.0kGy Irradiation Dose Delivered: 31.6kGy to 44.9kGy

Validated Sterile Product: Validation Sterile packets available upon request.

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

**AAMI/ISO 11137)** 

**Expiration Date:** 10/2017

QC Supervisor

coc@contecinc.com

## **Certificate Of Processing**

Prepared for CONTEC INC

## Gamma Process Run ID 462734



Product Code	Product Lot Number	Quantity	UOM
21914-772	436496-*-*-1	48	cs
21914-772	436497-*-*-1	48	cs
492226-939	433276-"-"-1	36	CS
492226-944	433173-*-*-1	36	CS
492238-960	434822-*-*-1	18	cs
ELMOP3IR	439567-*-*-1	60	cs
MEQT0002	436737-*-*-1	72	CS
MEQT0002	436739-*-*-1	72	cs
MEQT0002	437318-*-*-1	72	CS
MVK-MOP-IR	434551-*-*-1	18	CS
MVK-MOP-IR	434552-"-"-1	18	CS
PN-99IR	432708-*-*-1	26	CS
TLVKMOPIR	440699-*-*-1	18	cs

Processing Run Start Date/Time:

12-Oct-2015 11:46:49 pm

Approx. Downtime (hours):

2.70

Processing Run End Date/Time:

13-Oct-2015 02:02:17 pm

Minimum Specified Dose (kGy):

25.0

Minimum Delivered Dose (kGy):

31.6

Maximum Specified Dose (kGy):

50.0

Maximum Delivered Dose (kGy):

44,9

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 10/14/2015 at 8:24 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 dos/metry system used.