Date: May 01, 2014



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

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: 349393-\*-\*-1
Manufacturing Date: 04/25/2014
Run Number: 42969A

Irradiation Dose Specified: 25kGy to 50kGy Irradiation Dose Delivered: 28.1kGy to 42.3kGy

Validated Sterile Product: Validation Sterile packets available upon request.

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

AAM1/ISO 11137)

Expiration Date: 04/2016

QC Supervisor

coc@contecinc.com

# **Certificate Of Processing**

### Prepared for CONTEC INC



Isomedix Services

Gamma Process Run ID 42969A

Product Code	<b>Product Lot Number</b>	Quantity	UOM
492226-944	340157-*-*-1	36	CS
MEQT0002	349393-*-*-1	72	cs
MVK-MOP-IR	345314-*-*-1	18	CS
MVK-MOP-IR	345315-*-*-1	18	cs
MVK-MOP-IR	346689-*-*-1	18	cs
PN-99IR	344705-*-*-1	26	cs
SB32IR	337214-*-*-1	48	CS
SB32IR	337215-*-*-1	16	cs
VKMX0250	333167-*-*-1	24	cs

Processing Run Start Date/Time:

30-Apr-2014 09:04:37 am

Approx. Downtime (hours):

1.00

Processing Run End Date/Time:

30-Apr-2014 07:34:11 pm

Minimum Specified Dose (kGy):

25.0

Minimum Delivered Dose (kGy):

28.1

Maximum Specified Dose (kGy):

50.0

Maximum Delivered Dose (kGy):

42.3

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

## Signature Manifest

Reviewed and E-Signed By

Shawn Laurent (Production Supervisor)

Document Content Revision: 1

Signed On 5/1/2014 at 5:44 AM UTC / GMT Offset (hh:mm): -4:00

#### **Processing Location:**

Fax: 864-582-4075

STERIS Isomedix Services 2072 Southport Road Spartanburg, SC 29306 Phone: 864-582-3041 Operating facilities are in compilance 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.