

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: July 03, 2013 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: 291295-\*-\*-1 Manufacturing Date: 06/28/2013 Run Number: 40996A

Irradiation Dose Specified: 25kGy to 50kGy Irradiation Dose Delivered: 28.1kGy to 41.2kGy

Validated Sterile Product: Validation Sterile packets available upon request.

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

AAM1/ISO 11137)

**Expiration Date:** 06/2015

**QC** Supervisor

coc@contecinc.com

# **Certificate Of Processing**

Prepared for CONTEC INC



## Gamma Process Run ID 40996A

Product Code	Product Lot Number	Quantity	UOM
492226-946	288349-*-*-1	36	CS
492226-946	288350-*-*-1	36	CS
492226-946	288351-*-*-1	36	CS
ELMOP3IR	291833-*-*-1	60	CS
EZMP0150	290998-*-*-1	16	CS
LWPS0007	291964-*-*-1	20	CS
MEQT0002	291295-*-*-1	70	CS
MVK-MOP-IR	284156-*-*-1	18	CS
MVK-MOP-IR	284157-*-*-1	18	CS
MVK-MOP-IR	287364-*-*-1	18	cs

Processing Run Start Date/Time:

02-Jul-2013 01:41:28 pm

Approx. Downtime (hours):

0.00

Processing Run End Date/Time:

03-Jul-2013 12:56:38 am

Minimum Specified Dose (kGy):

25.0

Minimum Delivered Dose (kGy):

28.1

Maximum Specified Dose (kGy):

50.0

Maximum Delivered Dose (kGy):

41.2

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

# Signature Manifest



Reviewed and E-Signed By

Mark Williams (Production Supervisor)

Document Content Revision: 1

Signed On 7/3/2013 at 9:32 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.