

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: November 12, 2012 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: 253473-\*-\*-1 Manufacturing Date: 11/02/2012 Run Number: 39475A

Irradiation Dose Specified: 25kGy to 50kGy Irradiation Dose Delivered: 36kGy to 48.3kGy

Validated Sterile Product: Validation Sterile packets available upon request.

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

AAM1/ISO 11137)

11/2014 **Expiration Date:** 

**QC** Supervisor

coc@contecinc.com

# **Certificate Of Processing**

## Prepared for CONTEC INC

### Gamma Process Run ID 39475A



Product Code	Product Lot Number	Quantity	UOM
21914-772	252077-*-*-1	72	CS
492226-944	251303-*-*-1	36	cs
492226-946	251417-*-*-1	36	cs
LWCS0033	252316-*-*-1	36	cs
LWCS0033	252317-*-*-1	36	CS
LWQS0002	250276-*-*-1	36	cs
LWQS0002	250277-*-*-1	35	CS
MEQT0002	253473-*-*-1	68	cs
MVK-MOP-IR	251233-*-*-1	18	CS

251234-\*-\*-1

Processing Run Start Date/Time:

08-Nov-2012 09:00:50 am

Approx. Downtime (hours):

2.00

18

CS

Processing Run End Date/Time:

09-Nov-2012 08:34:05 pm

Minimum Specified Dose (kGy):

25.0

Minimum Delivered Dose (kGy):

36.0

Maximum Specified Dose (kGy):

50.0

Maximum Delivered Dose (kGy):

48.3

## Signature Manifest



MVK-MOP-IR

Approved By:

Brian Kenning (Production Supervisor)

Document Content Revision: 1

Signed On 11/11/2012 at 9:42 AM UTC / GMT Offset (hh:mm): -5:00

#### **Processing Location:**

STERIS Isomedix Services 2072 Southport Road Spartanburg, SC 29306 Phone: 864-582-3041 Fax: 864-582-4075 The product run / load described above was processed in accordance with STERIS Isomedix Services Quality System requirements and the Customer-approved process parameters. STERIS Isomedix Services facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA). STERIS Isomedix Services operates under a quality system which meets the requirements of the FDA QSR and EN ISO 13485:2003. STERIS Isomedix Services adheres to requirements provided through EN ANSI/AAMI/ISO 11137:2006, EN ANSI/AAMI/ISO 11135:2007.