

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: December 16, 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: 324005-*-*-1 Manufacturing Date: 12/10/2013 Run Number: 42079A

Irradiation Dose Specified: 25kGy to 50kGy Irradiation Dose Delivered: 28.6kGy 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: 12/2015

QC Supervisor

coc@contecinc.com

Certificate Of Processing

Prepared for CONTEC INC

STERIS

Gamma Process Run ID 42079A

Product Code	Product Lot Number	Quantity	UOM
EL-MOP-IR	323077-*-*-1	18	CS
LWPS0027	324083-*-*-1	36	CS
MEQT0002	324005-*-*-1	72	CS
MVK-MOP-IR	323705-*-*-1	18	cs
TBLVKMOPIR	317509-*-*-1	16	CS
TLVKMOPIR	322906-*-*-1	18	CS

Processing Run Start Date/Time:

13-Dec-2013 01:26:54 pm

Approx. Downtime (hours):

0.40

Processing Run End Date/Time:

13-Dec-2013 09:49:44 pm

Minimum Specified Dose (kGy):

25.0

Minimum Delivered Dose (kGy):

28.6

Maximum Specified Dose (kGy):

Maximum Delivered Dose (kGy):

50.0

42.3

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

Signature Manifest



Reviewed and E-Signed By

Byron Morris (Production Supervisor)

Document Content Revision: 1

Signed On 12/14/2013 at 5:37 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

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.

06-Mar-2013