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**CERTIFICATE OF CONFORMANCE AND STERILITY**

Date: August 11, 2014

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: 365711-\*-\*-1  
Manufacturing Date: 08/05/2014  
Run Number: 43603A  
Irradiation Dose Specified: 25kGy to 50kGy  
Irradiation Dose Delivered: 30.6kGy to 46.6kGy  
Validated Sterile Product: Validation Sterile packets available upon request.  
Sterility Assurance Level:  $10^{-6}$  (SAL determined by test method  
AAM1/ISO 11137)  
Expiration Date: 08/2016

QC Supervisor  
coc@contecinc.com

# Certificate Of Processing

Prepared for CONTEC INC



Isomedix Services

Gamma Process Run ID 43603A


<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
33502-730	363072-*-*1	24	CS
EL-MOP-IR	365445-*-*1	18	CS
LVK-MOP-IR	362901-*-*1	18	CS
MEQT0002	365711-*-*1	72	CS
MVK-MOP-IR	360888-*-*1	18	CS
TASK0650	367785-*-*1	24	CS
TASK0650	367786-*-*1	24	CS
TASK0650	367787-*-*1	24	CS
VKMX0250	362923-*-*1	24	CS
VKMX0350	350495-*-*1	24	CS

Processing Run Start Date/Time:	09-Aug-2014 04:30:52 am	Approx. Downtime (hours):	0.00
Processing Run End Date/Time:	09-Aug-2014 02:32:12 pm		

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	30.6
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	46.6

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

## Signature Manifest

Reviewed and E-Signed By  
 **Magilis Cruz (QS/RC Analyst)**

Document Content Revision: 1

Signed On 8/11/2014 at 9:37 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.