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## CERTIFICATE OF CONFORMANCE AND STERILITY

Date: July 07, 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.

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Product Code: MEQT0002  
Lot Number: 357545-\*-\*-\*1  
Manufacturing Date: 07/02/2014  
Run Number: 43395A  
Irradiation Dose Specified: 25kGy to 50kGy  
Irradiation Dose Delivered: 31.5kGy to 45.2kGy  
Validated Sterile Product: Validation Sterile packets available upon request.  
Sterility Assurance Level:  $10^{-6}$  (SAL determined by test method AAM1/ISO 11137)  
Expiration Date: 07/2016

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QC Supervisor  
coc@contecinc.com

# Certificate Of Processing

Prepared for CONTEC INC



Isomedix Services

Gamma Process Run ID 43395A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
21914-772	357458-*-*-1	48	CS
21914-772	357459-*-*-1	48	CS
21914-772	357460-*-*-1	48	CS
21914-772	361080-*-*-1	48	CS
33502-730	355061-*-*-1	24	CS
33502-730	356840-*-*-1	24	CS
BLVKMOPIR	358389-*-*-1	18	CS
EL-MOP-IR	356226-*-*-1	18	CS
LVK-MOP-IR	354558-*-*-1	18	CS
MEQT0002	357545-*-*-1	72	CS
TASK0650	361104-*-*-1	48	CS
VKMX0250	349054-*-*-1	24	CS

Processing Run Start Date/Time: 05-Jul-2014 11:24:37 pm

Approx. Downtime (hours): 3.50

Processing Run End Date/Time: 06-Jul-2014 12:58:03 pm

<b>Minimum Specified Dose (kGy):</b>	<b>25.0</b>	<b>Minimum Delivered Dose (kGy):</b>	<b>31.5</b>
<b>Maximum Specified Dose (kGy):</b>	<b>50.0</b>	<b>Maximum Delivered Dose (kGy):</b>	<b>45.2</b>

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

## Signature Manifest

Reviewed and E-Signed By



**Stephanie Caldwell (QS/RC Technician)**

Document Content Revision: 1

Signed On 7/7/2014 at 9:09 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.