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CERTIFICATE OF CONFORMANCE AND STERILITY

Date: April 23, 2015

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: 405784-*-*1
Manufacturing Date: 04/14/2015
Run Number: 45167A
Irradiation Dose Specified: 25.0kGy to 50.0kGy
Irradiation Dose Delivered: 26.1kGy to 36.3kGy
Validated Sterile Product: Validation Sterile packets available upon request.
Sterility Assurance Level: 10^{-6} (SAL determined by test method
AAMI/ISO 11137)
Expiration Date: 04/2017

QC Supervisor
coc@contecinc.com

Certificate Of Processing

Prepared for CONTEC INC



STERIS

Isomedix Services

Gamma Process Run ID 45167A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
LVK-MOP-IR	403506-*-*-1	18	CS
MEQT0002	405784-*-*-1	72	CS
MVK-MOP-IR	403518-*-*-1	18	CS
MVK-MOP-IR	403519-*-*-1	18	CS
MVK-MOP-IR	404498-*-*-1	18	CS
PN-99IR	401402-*-*-1	26	CS

Processing Run Start Date/Time:	21-Apr-2015 07:49:37 pm	Approx. Downtime (hours):	0.10
Processing Run End Date/Time:	22-Apr-2015 04:30:13 am		

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	26.1
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	36.3

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

Signature Manifest

Reviewed and E-Signed By
Princess Shaw (QS/RC Technician)
Document Content Revision: 1

Signed On 4/22/2015 at 3:13 PM
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.