



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: April 21, 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: 405783-*-*1
Manufacturing Date: 04/12/2015
Run Number: 45153A
Irradiation Dose Specified: 25.0kGy to 50.0kGy
Irradiation Dose Delivered: 26.9kGy to 42.5kGy
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 45153A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
21914-772	400553-**-1	48	CS
ELMOP3IR	406372-**-1	60	CS
EL-MOP-IR	403548-**-1	18	CS
EL-MOP-IR	403967-**-1	18	CS
EL-MOP-IR	404582-**-1	18	CS
MEQT0002	405783-**-1	72	CS
MVK-MOP-IR	402365-**-1	18	CS
NWPZ0002	138319-**-1	60	CS

Processing Run Start Date/Time:	18-Apr-2015 10:57:20 am	Approx. Downtime (hours):	0.20
Processing Run End Date/Time:	18-Apr-2015 10:19:32 pm		

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	26.9
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	42.5

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 4/20/2015 at 9:24 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.