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CERTIFICATE OF CONFORMANCE AND STERILITY

Date: February 10, 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: 396219-*-*1
Manufacturing Date: 02/05/2015
Run Number: 44736A
Irradiation Dose Specified: 25kGy to 50kGy
Irradiation Dose Delivered: 31.6kGy to 44.5kGy
Validated Sterile Product: Validation Sterile packets available upon request.
Sterility Assurance Level: 10^{-6} (SAL determined by test method
AAMI/ISO 11137)
Expiration Date: 02/2017

QC Supervisor
coc@contecinc.com

Certificate Of Processing

Prepared for CONTEC INC



Isomedix Services

Gamma Process Run ID 44736A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
21914-772	394200-*-*1	48	CS
21914-772	394990-*-*1	48	CS
21914-772	394991-*-*1	48	CS
492226-944	396700-*-*1	36	CS
492226-944	396701-*-*1	36	CS
EL-MOP-IR	395904-*-*1	18	CS
LVK-MOP-IR	394896-*-*1	18	CS
MEQT0002	396011-*-*1	72	CS
MEQT0002	396219-*-*1	72	CS
MVK-MOP-IR	393525-*-*1	18	CS
MVK-MOP-IR	393526-*-*1	18	CS
MVK-MOP-IR	393527-*-*1	18	CS
NWPZ0002	109949-*-*7	2	CS
NWPZ0002	132958-*-*2	22	CS
NWPZ0002	136283-*-*1	24	CS
Samples	ETR1472-*-*1	1	CS
Samples	ETR1473-*-*1	1	CS

Processing Run Start Date/Time:	07-Feb-2015 11:47:12 pm	Approx. Downtime (hours):	0.10
Processing Run End Date/Time:	08-Feb-2015 01:25:18 pm		

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	31.6
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	44.5

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

Signature Manifest

Reviewed and E-Signed By
☒ **Ryan Rose (QS/RC Analyst 1)**

Document Content Revision: 1

Signed On 2/10/2015 at 9:38 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.