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CERTIFICATE OF CONFORMANCE AND STERILITY

Date: January 12, 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: 391587-*-*1
Manufacturing Date: 01/05/2015
Run Number: 44555A
Irradiation Dose Specified: 25kGy to 50kGy
Irradiation Dose Delivered: 26.2kGy to 46.3kGy
Validated Sterile Product: Validation Sterile packets available upon request.
Sterility Assurance Level: 10^{-6} (SAL determined by test method
AAMI/ISO 11137)
Expiration Date: 01/2017

QC Supervisor
coc@contecinc.com

Certificate Of Processing

Prepared for CONTEC INC



Isomedix Services

Gamma Process Run ID 44555A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
21914-772	390597-**-1	48	CS
21914-772	390598-**-1	48	CS
BKTBAG	384098-**-1	34	CS
BLVKMOPIR	386217-**-1	18	CS
ELMOP3IR	388694-**-1	36	CS
ELMOP3IR	388695-**-1	36	CS
EZMP0150	386887-**-1	16	CS
LWCS0027	388809-**-1	18	CS
LWCS0027	390664-**-1	18	CS
MEQT0002	391587-**-1	72	CS
MEQT0002	391588-**-1	72	CS
NWPZ0001	134929-**-1	240	CS
SB32IR	380530-**-1	48	CS
SB32IR	391381-**-1	48	CS
VKMX0150	385411-**-1	24	CS

Processing Run Start Date/Time:	10-Jan-2015 12:49:17 pm	Approx. Downtime (hours):	0.90
Processing Run End Date/Time:	11-Jan-2015 06:28:46 am		

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	26.2
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	46.3

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 1/12/2015 at 8:44 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.