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CERTIFICATE OF CONFORMANCE AND STERILITY

Date: January 26, 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: 394679-*-*1
Manufacturing Date: 01/22/2015
Run Number: 44645A
Irradiation Dose Specified: 25kGy to 50kGy
Irradiation Dose Delivered: 30.5kGy to 48.4kGy
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 44645A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
115-1724	393824-*-*-1	48	CS
21914-772	390601-*-*-1	48	CS
492226-939	392808-*-*-1	18	CS
BLVKMOPIR	392391-*-*-1	18	CS
ELMOP3IR	393350-*-*-1	60	CS
EL-MOP-IR	392328-*-*-1	18	CS
EL-MOP-IR	392329-*-*-1	18	CS
EL-MOP-IR	392330-*-*-1	18	CS
GOGLIR	393503-*-*-1	60	CS
LVK-MOP-IR	388709-*-*-1	18	CS
MEQT0002	394679-*-*-1	72	CS
MVK-MOP-IR	390756-*-*-1	18	CS
SB32IR	391382-*-*-1	64	CS
TLVKMOPIR	384246-*-*-1	18	CS
VK-MOP-IR	394907-*-*-1	18	CS

Processing Run Start Date/Time: 24-Jan-2015 03:36:19 pm

Approx. Downtime (hours): 0.30

Processing Run End Date/Time: 25-Jan-2015 07:12:23 am

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	30.5
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	48.4

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 1/26/2015 at 11:56 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.