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CERTIFICATE OF CONFORMANCE AND STERILITY

Date: September 08, 2014

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: 373270-*-*-1
Manufacturing Date: 09/04/2014
Run Number: 43784A
Irradiation Dose Specified: 25kGy to 50kGy
Irradiation Dose Delivered: 29.7kGy to 43.7kGy
Validated Sterile Product: Validation Sterile packets available upon request.
Sterility Assurance Level: 10^{-6} (SAL determined by test method
AAM1/ISO 11137)
Expiration Date: 09/2016

QC Supervisor
coc@contecinc.com

Certificate Of Processing

Prepared for CONTEC INC



Isomedix Services

Gamma Process Run ID 43784A

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
492226-939	371160-*-*-1	18	CS
MEQT0002	373270-*-*-1	72	CS

Processing Run Start Date/Time:	07-Sep-2014 11:45:43 am	Approx. Downtime (hours):	0.90
Processing Run End Date/Time:	07-Sep-2014 08:30:19 pm		

Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	29.7
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	43.7

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

Signature Manifest

Reviewed and E-Signed By
☒ **Stephanie Caldwell (QS/RC Technician)**
Document Content Revision: 1

Signed On 9/8/2014 at 11:41 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.