

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: 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

| Product Code | Product Lot Number | Quantity | UOM |
|--------------|---------------------------|----------|-----|
| 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):

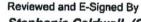
50.0

Maximum Delivered Dose (kGy):

43.7

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

Signature Manifest



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.