# Certificate of Conformance and Sterility

This certification is provided as full assurance that the following product code and lot number were manufactured in accordance via a Quality System certified to ISO 9001 with prescribed procedures and specifications.

| | |
|---|---|
| Product Code: | VKSE0350 |
| Lot Number: | 727093-0-0-1 |
| Manufacturing Date: | 09/04/2019 |
| Expiration Date: | 09/2021 |

**Sterility**

| | |
|---|---|
| Gamma Processing Run ID: | 56093A |
| Irradiation Dose Specified: | 30 kGy to 50 kGy |
| Irradiation Dose Delivered: | 32.4 kGy to 44.0 kGy |
| Validated Sterile Product: | Validation Sterile packets available upon request. |
| Sterility Assurance Level: | 10^-6 (SAL determined by test method AAMI/ISO 11137) |

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# Certificate Of Processing

Prepared for **CONTEC INC**

STERIS

## Gamma Process Run ID **56093A**

| Product Code | Product Lot Number | Quantity | UOM |
|---|---|---|---|
| LWLE0002 | 723403-0-0-1 | 16 | CS |
| VKSE0350 | 727093-0-0-1 | 30 | CS |

Processing Run Start Date/Time: 13-Sep-2019 06:55:57 pm

Processing Run End Date/Time: 14-Sep-2019 12:21:58 am

Approx. Downtime (hours): 0.00

**Minimum Specified Dose (kGy):** **25.0**

**Maximum Specified Dose (kGy):** **50.0**

**Minimum Delivered Dose (kGy):** **32.4**

**Maximum Delivered Dose (kGy):** **44.0**

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

## Signature Manifest

Reviewed and E-Signed By

***Brandie McCurry (QS/RC Technician)***

Document Content Revision: 1

Signed On 9/16/2019 at 12:51 PM

UTC / GMT Offset (hh:mm): -4:00

**Processing Location:**
STERIS
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, and in alignment with the applicable standard, EN ANSI/AAMI/ISO 11137 or EN ANSI/AAMI/ISO 11135. For items processed with gamma irradiation, STERIS certifies that these items received the indicated doses within the precision and accuracy of the dosimetry system used.