



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:	EZMP0350
Lot Number:	802863-0-0-1
Manufacturing Date:	09/15/2020
Expiration Date:	09/2022

Sterility

Gamma Processing Run ID:	58617A
Irradiation Dose Specified:	30 kGy to 50 kGy
Irradiation Dose Delivered:	33.7 kGy to 45.0 kGy
Sterility Assurance Level:	10 ⁻⁶ (SAL determined by test method AAMI/ISO 11137)

QC Supervisor
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Monday, September 21, 2020

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DID: 15001B

Certificate Of Processing

Prepared for CONTEC INC



Gamma Process Run ID **58617A**

<u>Product Code</u>	<u>Product Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
BLVKMOPIR	791146-0-0-1	18	CS
BLVKMOPIR	791148-0-0-1	18	CS
EZMP0350	802863-0-0-1	16	CS
VK-MOP-IR	800484-0-0-1	18	CS
VK-MOP-IR	800485-0-0-1	18	CS
VK-MOP-IR	800486-0-0-1	18	CS
VKMX0275	800683-0-0-1	24	CS
VKMX0275	802873-0-0-1	24	CS
VKMX0375	797325-0-0-1	24	CS
VKMX0375	800491-0-0-1	24	CS
VKMX0375	802874-0-0-1	24	CS
VKSE0250	801676-0-0-1	24	CS
VKSE0250	801677-0-0-1	24	CS
VKSE0250	801678-0-0-1	24	CS
VKSE0250	801680-0-0-1	24	CS
VKSE0250	803135-0-0-1	24	CS

Processing Run Start Date/Time: 17-Sep-2020 05:09:40 pm Approx. Downtime (hours): 0.30
Processing Run End Date/Time: 18-Sep-2020 01:06:05 am

Minimum Specified Dose (kGy):	30.0	Minimum Delivered Dose (kGy):	33.7
Maximum Specified Dose (kGy):	50.0	Maximum Delivered Dose (kGy):	45.0
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 9/18/2020 at 8:48 AM
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.