

STERIS: Gamma Certificate Of Processing

Prepared for: [REDACTED] (6526)

Gamma Process Run ID: 9003-135A

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
aa	34234	33	Case
Validation Reference Number: AA_1290			
aa	34234	83	Case
Validation Reference Number: AA_1290			

PO Number: 324566

Processing Run Start Date: 05-Apr-17 06:31 PM

Approx. Downtime (hours): 0.00

Processing Run End Date: 05-Apr-17 06:32 PM

Minimum Specified Dose (kGy): 4.0

Minimum Delivered Dose (kGy): 4.2

Maximum Specified Dose (kGy): 6.0

Maximum Delivered Dose (kGy): 5.9

Customer Field #1: Customer Requested Information

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

Signature Manifest

Reviewed and E-Signed By: **Ronald Nyegard (Director, Operations Systems Development)**

Date/Time E-Signed: 2018-02-08 11:38 PM

Document Content Revision: 1

Operating facilities is 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 EN ANSI/AAMI/ISO 11137. STERIS certifies that these processed items received the indicated doses within the precision and accuracy of the dosimetry system used. Legal Entity: Synergy Health Sterilisation UK, a STERIS Company.

Processing Location

9260 Progress Pwky
Mentor OH 44060
Phone: 858-324-1063