



BULK - CERTIFICATE OF STERILITY

CERTIFICATE / LOAD NO: 07014
STERIS TRACKING PCN: 1224-36810
STERILIZATION DATE: 2024-07-14
CERTIFICATE ISSUE DATE: 2024-07-15

The following product(s) / lot number(s) were sterilized using the electron beam process which utilizes high energy electrons as its radiation source.

The electrons, which are produced by normal electrical current, are accelerated to near the speed of light by means of a linear accelerator.

This process was completed by Steris AST, Saxonburg, PA, USA.

PRODUCTS:

Catalog No: 101 & 301
Lot Number(s): 06054, 06064, 06124, 06134, 06184, 06194,
06244, 06254, 07094 & 07104
Expiration Date: 2026-01-31

Catalog No: 105 & 305
Lot Number(s): 07024 & 07034
Expiration Date: 2026-01-31

Catalog No: 110 & 310
Lot Number(s): 06274 & 06284
Expiration Date: 2026-01-31

ISSUED AND AUTHORIZED BY:

John R Kelch
President

A handwritten signature in black ink, appearing to read 'John R Kelch', is written over a light blue circular background element.

Ashton Pumpmatic

7670 McEwen Road
Dayton, Ohio 45459

Phone: 937.424.1380

Toll Free: 800.395.1012

Fax: 937.424.1390

www.pumpmatic.com

STERIS: Electron Beam Certificate Of Processing

Prepared ForASHTON PUMPMATIC INC (1606)

Ebeam Process RunID1224-36810

Product Code	Lot Number	Quantity	UOM
101	06054	40	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
101	06064	32	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
101	06124	40	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
101	06134	32	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
101	06184	40	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
101	06194	32	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
101	06244	40	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
101	06254	32	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
101	07094	40	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
101	07104	32	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
105	07024	40	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
105	07034	32	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
110	06274	40	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		
110	06284	32	Case
Validation Reference Number:	P2180644T1-T3P2180645T1-T3		

Processing Run Start Date14-Jul-2024 11:33 AM

Processing Run End Date14-Jul-2024 2:13 PM

Specified Dose Range (kGy)	13.2 - 25.0	Calculated Min Dose (kGy)	13.6
		Calculated Max Dose (kGy)	22.9

PO Number: 2024115

SPSA/Load Spec: ASH01

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

E-Beam Process Run Approval authorized by STERIS

DateTime Esigned 14-Jul-2024 2:31 PM

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 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.

Processing Location

7225 North Noah Drive
Saxonburg, PA 16056
Phone: 724-352-3580

STERILE PRODUCT RELEASE

TO: Shipping and Receiving

Date: 7/16/2024

CC: Sterilization Records

Catalog Series 1XX / 3XX product marked with Ashton Pumpmatic Inc, Sterilization Load No. 07014

was sterilized by:

☒ Electron Beam at Steris AST

has been verified as sterile and may be shipped through interstate commerce. The following quantities of product are involved in this release:

SERVICES PCN NO: 1224-36810

1 0 1 / 3 0 1	
Total #	
Cases	360
Lot No	# Cases
06054	40
06064	32
06124	40
06134	32
06184	40
06194	32
06244	40
06254	32
07094	40
07104	32

1 0 5 / 3 0 5	
Total #	
Cases	68
Lot No	# Cases
07024	38
07034	30

1 1 0 / 3 1 0	
Total #	
Cases	72
Lot No	# Cases
06274	40
06284	32

Expiration Date: 2026-01-31

PO No: 2024115

Date: 07/11/24

Disposition for Testing and Retains:

Grand Total Cases: 500



Signature, President

VERIFICATION OF RETURNED GOODS

Load No: 07014

Date: 7/16/2024

PO No: 2024115

☒ Electron Beam at Steris AST

SERVICES PCN NO: 1224-36810

1 0 1 / 3 0 1

1 0 5 / 3 0 5

1 1 0 / 3 1 0

Lot No	# Cases
06054	40
06064	32
06124	40
06134	32
06184	40
06194	32
06244	40
06254	32
07094	40
07104	32
Total # Cases	<u>360</u>

Lot No	# Cases
07024	38
07034	30
Total # Cases	<u>68</u>

Lot No	# Cases
06274	40
06284	32
Total # Cases	<u>72</u>

Grand Total Cases: 500

Counted By:

JRK

Verified By:

JEK