

# **BULK - CERTIFICATE OF STERILITY**

CERTIFICATE / LOAD NO:	10014
STERIS TRACKING PCN:	1224-37947
STERILIZATION DATE:	2024-09-29
CERTIFICATE ISSUE DATE:	2024-10-01

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: Lot Number(s): Expiration Date: 101 & 301 07254, 07294, 08064, 08074, 09104 & 09114 2026-04-30

Catalog No: Lot Number(s): Expiration Date: 105 & 305 08204 & 08214 2026-04-30

Catalog No: Lot Number(s): Expiration Date: 110 & 310 08297, 09034, 09064 & 09094 2026-04-30

ISSUED AND AUTHORIZED BY:

John R Kelch President

John R Kelel

#### **Ashton Pumpmatic**

7670 McEwen Road Dayton, Ohio 45459

Phone: 937.424.1380 Toll Free: 800.395.1012 Fax: 937.424.1390 www.pumpmatic.com

#### STERILE PRODUCT RELEASE

TO:
Shipping and Receiving
Date:
10/1/2024

CC:
Sterilization Records
Image: Catalog Series XX / 3XX product marked with Ashton Pumpmatic Inc, Sterilization No.
10014

Image: Catalog Series XX / 3XX product marked with Ashton Pumpmatic Inc, Sterilization No.
10014

Image: Catalog Series XX / 3XX product marked with Ashton Pumpmatic Inc, Sterilization No.
10014

Image: Catalog Series Inc.

Image: Catal

SERVICES PCN NO: 1224-37947

101/301			105/305		1 1 0 / 3 1 0		
Total #		Total #		Total #			
Cases	216	Cases	72	Cases	140		
Lot No	# Cases	Lot No	# Cases	Lot No	# Cases		
07254	40	08204	40	08294	38		
07294	32	08214	32	09034	30		
08064	40			09064	32		
08074	32			09094	40		
09104	40						
09114	32						
Expiration	Date: 2026-	04-30	-	PO No: 2	024155		
				Date: 09/15/2	2024		
Dispositio	n for Testing and R	letains:					
				Grand Total Case	es: <u>428</u>		
				John R.K	élel		
			-	V			

Signature, President

## VERIFICATION OF RETURNED GOODS

Load No:	10014	Date:	10/1/2024
PO No:	2024155	-	

Electron Beam at Steris AST

SERVICES PCN NO: 1224-37947

101/301 105/305 110/310

Lot No	# Cases	Lot No	# Cases	Lot No	# Cases
07254	40	08204	40	08294	38
07294	32	08214	32	09034	30
08064	40			09064	32
08074	32			09094	40
09104	40				
09114	32				
Total # Cases	216	Total # Cases	72	Total # Cases	140
				Grand Total Cases:	428
Counted	By:		Ņ	Verified By:	
JR	к			JEK	

Form QA 106 (Rev 2018-04)

#### **STERIS: Electron Beam Certificate Of Processing**

Prepared For Ebeam Process RunID ASHTON PUMPMATIC INC (1606) 1224-37947

Produ	ct Code	Lot Number	Quanti	ty <u>UOM</u>	
101		07254	4	0 Case	
	Validation Reference Number:	P2180644T1-T3P2180	0645T1-T3		
101		07294	3	2 Case	
	Validation Reference Number:	P2180644T1-T3P2180	0645T1-T3		
101		08064	4	0 Case	
	Validation Reference Number:	P2180644T1-T3P2180	)645T1-T3		
101		08074	3	2 Case	
	Validation Reference Number:	P2180644T1-T3P2180	)645T1-T3		
101		09104	4	0 Case	
	Validation Reference Number:	P2180644T1-T3P2180	0645T1-T3		
101		09114	3	2 Case	
	Validation Reference Number:	P2180644T1-T3P2180	0645T1-T3		
105		08204	4	0 Case	
	Validation Reference Number:	P2180644T1-T3P2180	)645T1-T3		
105		08214	:	2 Case	
	Validation Reference Number:	P2180644T1-T3P2180	)645T1-T3		
110		08294		0 Case	
	Validation Reference Number:	P2180644T1-T3P2180	)645T1-T3		
110		09034	:	2 Case	
	Validation Reference Number:	P2180644T1-T3P2180	)645T1-T3		
110		09064		32 Case	
	Validation Reference Number:	P2180644T1-T3P2180	0645T1-T3		
110		09094		0 Case	
	Validation Reference Number:	P2180644T1-T3P2180	0645T1-T3		
Proces	ssing Run Start Date	29-Sep-2024 4:20 AM			
Proces	ssing Run End Date	29-Sep-2024 6:15 AM			
Spec	ified Dose Range (kGy)	13.2 - 25.0	Calculated Min Dose (kGy)	13.5	
			Calculated Max Dose (kGy)	23.6	

PO Number: 2024155

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 29-Sep-2024 6:26 AM

Operating facilities are in compliance with applicable state and federal regulations (FDA, NRC, EPA, and OSHA) and Document ID: 146399