

# **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: 101 & 301

Lot Number(s): 07254, 07294, 08064, 08074, 09104 & 09114

Expiration Date: 2026-04-30

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

Catalog No: 110 & 310

Lot Number(s): 08294, 09034, 09064 & 09094

Expiration Date: 2026-04-30

ISSUED AND AUTHORIZED BY: John R Kelch President

John Rkelel

**Ashton Pumpmatic** 

7670 McEwen Road Dayton, Ohio 454<u>59</u>

**Phone:** 937.424.1380 **Toll Free:** 800.395.1012

**Fax:** 937.424.1390 www.pumpmatic.com

### STERILE PRODUCT RELEASE

TO:	Shipping a	nd Receiving					Date:	10/1/2024	
CC:	Sterilization	n Records							
Catalog Serie	s 1XX / 3XX	product mark	ked with	Ashton Pum	pmatic Inc, S	Sterlization	Load No.	10014	
was sterilized	by:		×	Flectron B	eam at Steri	s AST			
has been veri	fied as steril	e and mav be					e followina d	quantities of	
product are in				J			J	'	
			SERVICE	ES PCN NO	1224-3	37947			
	1 0 1 . Total #	/ 3 0 1 216	1 0 5 / 3 0 5 Total # Cases 72			1 1 0 / 3 1 0 Total # Cases 140			
	Cases Lot No	# Cases		Cases Lot No	# Cases		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							
	Evpiration	Doto: 2	026.04.1	20		DO No:	2024	155	
	Expiration Date: 2026-04						No: <u>2024155</u> ate: 09/15/2024		
	Disposition for Testing and Retains:				Date: 03/10/2024				
	Бізрозіцої	rior resuing a	and recta	III3.		Grand To	tal Cases:	428	
						Jo	lu R kel	eL_	
						Signature, President			

# **VERIFICATION OF RETURNED GOODS**

Date: 10/1/2024

Load No: \_\_\_\_\_10014

	PO No:	2024	155	_			
		X	Electron B	seam at Ster	is AST		
		SERVICES	PCN NO:	1224-	37947	_	
101	/301		1 0 5	/305		1 1 0	/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 Tot	al Cases:	428
Counted E	By:				Verified B	y:	
JRK					JEI	K	_

### STERIS: Electron Beam Certificate Of Processing

Prepared For ASHTON PUMPMATIC INC (1606)

Ebeam Process RunID 1224-37947

Produ	ct Code	Lot Number	Quantity	<u>UOM</u>
101		07254	40	Case
	Validation Reference Number:	P2180644T1-T3P218	0645T1-T3	
101		07294	32	Case
	Validation Reference Number:	P2180644T1-T3P218	0645T1-T3	
101		08064	40	Case
	Validation Reference Number:	P2180644T1-T3P218	0645T1-T3	
101		08074	32	Case
	Validation Reference Number:	P2180644T1-T3P218	0645T1-T3	
101		09104	40	Case
	Validation Reference Number:	P2180644T1-T3P218	0645T1-T3	
101		09114	32	Case
	Validation Reference Number:	P2180644T1-T3P218	0645T1-T3	
105		08204	40	Case
	Validation Reference Number:	P2180644T1-T3P218	0645T1-T3	
105		08214	32	. Case
	Validation Reference Number:	P2180644T1-T3P218	0645T1-T3	
110		08294	40	Case
	Validation Reference Number:	P2180644T1-T3P218	0645T1-T3	
110		09034	32	? Case
	Validation Reference Number:	P2180644T1-T3P218	0645T1-T3	
110		09064	32	2 Case
	Validation Reference Number:	P2180644T1-T3P218	0645T1-T3	
110		09094	40	) Case
	Validation Reference Number:	P2180644T1-T3P218	0645T1-T3	
Proces	ssing Run Start Date	29-Sep-2024 4:20 AN	1	
Proces	ssing Run End Date	29-Sep-2024 6:15 AN	1	
Specified 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

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