



## Certificate of Conformance, Analysis, 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.

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Product Code:	LWPS0007
Lot Number:	1160867-0-0-1
Manufacturing Date:	07/01/2025
Expiration Date:	07/2027

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### Analysis

Quantity of Particles Po:	3.43 millions/m <sup>2</sup>
Quantity of Fibers Po:	0.033 thousands/m <sup>2</sup>
Sorbency Rate:	1.0 seconds
Nonvolatile residue in DI:	0.0452 g/m <sup>2</sup>
Nonvolatile residue in IPA:	0.011 g/m <sup>2</sup>

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### Sterility

Gamma Processing Run ID:	1153-13590A
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	27.0 kGy to 42.4 kGy
Validated Sterile Product:	Validation Sterile packets available upon request.
Sterility Assurance Level:	10 <sup>-6</sup> (SAL determined by test method AAMI/ISO 11137)

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QC Supervisor  
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Friday, July 18, 2025

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# STERIS: Gamma Certificate Of Processing

Prepared For **CONTEC INC (1963)**

Gamma Process Run ID **1153-13590A**

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity</u>	<u>UOM</u>
492238-955	1161695-0-0-1	18	Case
492238-955	1162115-0-0-1	18	Case
492238-955	1162116-0-0-1	18	Case
492238-960	1162134-0-0-1	32	Case
HCMT0015	1160336-0-0-1	64	Case
HCMT0015	1161256-0-0-1	64	Case
LWPS0007	1160046-0-0-1	20	Case
LWPS0007	1160867-0-0-1	20	Case
LWPS0007	1160868-0-0-1	20	Case
LWPS0027	1160883-0-0-1	27	Case
492226-939	1158742-0-0-1	18	Case
492226-939	1161364-0-0-1	18	Case
492226-939	1161365-0-0-1	18	Case
76377-480	1148067-0-0-1	48	Case
76377-480	1148068-0-0-1	48	Case
76377-480	1162911-0-0-1	48	Case
76377-480	1162912-0-0-1	48	Case
PN-99IR	1162881-0-0-1	26	Case
PN-99IR	1162882-0-0-1	26	Case
PN-99IR	1162885-0-0-1	26	Case

Processing Run Start Date **15-Jul-2025 6:30 PM**

Processing Run End Date **16-Jul-2025 7:25 AM**

<b>Minimum Specified Dose (kGy)</b>	<b>25.0</b>	<b>Minimum Delivered Dose (kGy)</b>	<b>27.0</b>
<b>Maximum Specified Dose (kGy)</b>	<b>50.0</b>	<b>Maximum Delivered Dose (kGy)</b>	<b>42.4</b>

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

## Signature Manifest

Reviewed and E-Signed By: **Pachy Thor (Senior Quality Technician)**

Date/Time Esigned **16-Jul-2025 10:57 AM**

Document Content Revision 1

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 13485:2016, and in alignment with EN ANSI/AAMI/ISO 11137-1:2015.

Document ID: 154352

Product Code

Lot Number

Quantity UOM

Processing Location

2072 Southport Road  
Spartanburg, SC 29306  
United States of America  
Phone: 864-582-3041