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.

Product Code:	LWLE0001
Lot Number:	1131134-0-0-1
Manufacturing Date:	03/17/2025
Expiration Date:	03/2028

Analysis

Biaxial Shake Fibers:	0.026 thousands/m²
Biaxial Shake Particles 0.5µM:	5.7 millions/m²
Sorbency Rate:	1.0 seconds
Nonvolatile residue in DI:	0.00 g/m²
Nonvolatile residue in IPA:	0.0213 g/m²
Endotoxin:	<0.2667 EU/wipe

Sterility

Gamma Processing Run ID:	1153-12668A
Irradiation Dose Specified:	25.0 kGy to 50.0 kGy
Irradiation Dose Delivered:	25.9 kGy to 43.2 kGy
Sterility Assurance Level:	10^{-6} (SAL determined by test method AAMI/ISO 11137)

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STERIS: Gamma Certificate Of Processing

Prepared For CONTEC INC (1963)

Gamma Process Run ID 1153-12668A

Product Code	Lot Number	Quantity	UOM
492238-960	1129531-0-0-1	32	Case
LWPS0007	1132929-0-0-1	20	Case
LWPS0027	1128015-0-0-1	27	Case
LWPS0027	1128016-0-0-1	27	Case
LWQS0002	1131754-0-0-1	36	Case
LWQS0002	1131755-0-0-1	36	Case
MGMP0005	1133882-0-0-1	36	Case
MGMP0005	1134774-0-0-1	18	Case
HCMT0015	1131344-0-0-1	72	Case
HCMT0015	1131345-0-0-1	72	Case
HCMT0015	1131346-0-0-1	72	Case
HCMT0015	1131347-0-0-1	72	Case
HCMT0015	1131992-0-0-1	72	Case
HCMT0015	1131994-0-0-1	72	Case
LWLE0001	1131134-0-0-1	36	Case
LWLE0001	1131135-0-0-1	36	Case

Processing Run Start Date 31-Mar-2025 4:36 PM

Processing Run End Date 01-Apr-2025 5:12 AM

Minimum Specified Dose (kGy)	**25.0**	**Minimum Delivered Dose (kGy)**	**25.9**
Maximum Specified Dose (kGy)	**50.0**	**Maximum Delivered Dose (kGy)**	**43.2**

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

Signature Manifest

Reviewed and E-Signed By: **DeMarcus Rouse (Quality Analyst)**

DateTime Esigned 08-Apr-2025 9:30 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.

Processing Location

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

Document ID: 146930

Product Code	Lot Number	Quantity	UOM

charles river

Kinetic LAL Analysis by USP

Charles River Laboratories, Inc.
1023 Wappoo Road, Suite 43-B
Charleston, South Carolina 29407 USA
Phone: 843-402-4900
Fax: 843-766-7576

Customer: Contec, Inc	CT#: 250319	Report Date: 17 Apr 2025
Product/Device: LWLE0001		
Lot#: 1131134-0-0-1		Units Received: 20 ea
Potency: N/A	Endotoxin Limit: <1 EU/wipe	MVD/MVC: 1:1000 wipe/mL

Reagent Information

Reagent	Lot#	Rehydration Date	Expires
Kinetic LAL	T4643E	16 Apr 2025	30 Sep 2027
Control Standard Endotoxin	EX54032 (RSE/CSE ratio=14 EU/ng)	16 Apr 2025	31 Jan 2028
LAL Reagent Water	52011124 52100824	N/A	30 Nov 2026 31 Aug 2026

Test Results

Sample Preparation: Place 3 wipes from a pack into a beaker and extracted in 200mL of 37°C ± 1°C and extract at room temperature for 1 hour. Further 1:4 dilution made in LRW.

Kinetic Method: Kinetic Chromogenic	Standard Curve Range: 5-0.001 EU/mL	Correlation Coefficient: -0.9999	Slope: -0.2164
Unit ID	**Dilution Tested**	**Endotoxin Value**	**Datafile**
LWLE0001 1131134-0-0-1 1 of 3	1:266.67 wipe/mL	<0.2667 EU/wipe	CRL-1607192A-20250416-001
LWLE0001 1131134-0-0-1 2 of 3	1:266.67 wipe/mL	<0.2667 EU/wipe	CRL-1607192A-20250416-001
LWLE0001 1131134-0-0-1 3 of 3	1:266.67 wipe/mL	<0.2667 EU/wipe	CRL-1607192A-20250416-001

Product/Device Lot: LWLE0001 Lot#: 1131134-0-0-1

Endotoxin Test : (Circle one) (PASS) FAIL

Comments: (X) N/A (Check N/A if not applicable)

Analyst / Date:	Reviewed By / Date:	QA Approved By / Date:
17Apr2025	17Apr2025	21 APR 2025