

STERIS: Certificate Of Processing

Prepared **STIRILAB**
For
Ethylene Oxide Run ID **2002-3254**

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202403646	18

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

Other Information

Sterilization Batch Number 22A240728

Customer Specification ID: 37

Signature Manifest

Reviewed and E-Signed By: **Sarka Mejzlikova (Quality Analyst)**

DateTime Esigned 29-Jul-2024 5:39 PM

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, and in alignment with EN ANSI/AAMI/ISO 11135.

This Certificate becomes valid only with the Process Run Record Summary and Biological Indicators Incubation Certificate referring to applicable sterilization Batch Number.

Processing Location

STERIS AST CZ s.r.o.
Průmyslová zóna Košíkov 80
Velká Bíteš
595 01

*** End of Ethylene Oxide Certificate of Processing Document ***

Document ID: 13790

Certificate of Analysis



Customer: Stirilab s.r.o.
Address: Textilná 23
Ružomberok

SVK
03401

Job No: BI-CZE-VEL-202401269
Report Number: 115013
Date Issued: 05-Aug-2024
Page 1 of 1

Purchase Order No: 202403646
Product: STIRILAB 03 EQ-15%, Biological Indicator
Description: SGM Spore Strip – Bacillus atrophaeus ATCC #9372
Standard Method: ISO 11138-1:2017
Internal Work Instruction: CZE VEL : LW-LAB002
Customer Protocol: STIRILAB 03 EQ-15%

Date Sample(s) Received: 29-Jul-2024
Date On Test: 29-Jul-2024

Analytical Results

Label ID / Designation: 202403646

Lot / Sterilization Batch: 22A240728

Microbiology

Result

Biological Indicators

BI Lot Number	488
Number of samples	28
Positive Control Check 7	Positive
Number of positives	0
Negative Controls	Negative
Time on test	29/JUL/24 12:10:00
Time off Test	05/AUG/24 12:22:38

The results presented relate only to the items tested above as supplied by the Customer and received by the laboratory.

This test report should not be reproduced except in full, without prior written permission.

Released by:

Ria Collinsova

Laboratory Quality Analyst

Authorisation Date: 05-August-2024

Testing Facility
CZE Velka Bites
STERIS AST CZ s.r.o.
Prumyslová zóna Košíkov 80

Velká Bíteš

595 01

Process Run Record

Summary

STERIS AST CZ s.r.o.
Průmyslová zóna Košíkov 80
595 01 Velká Bíteš, Czech Republic
Tel: +420566562145
Fax:

Run ID:	315303	Pallet Count:	18	Batch No.:	22A240728
Customer:	routine_STIRILAB 03 EQ-15%	Checksum:	1886	Method:	STIRILAB 03 EQ-15%
Specification:	1.3				

1.Preconditioning

Equipment:	VB Precond G	Config. Rev.:	Pending		
Date Started:	27.07.2024 21:36:53	Date Completed:	28.07.2024 8:56:37	Duration:	11:19:44

1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:19:44	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	11:10:01	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	47,0 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	52,4 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	47,1 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	62,6 %	45,0 - 95,0 %	✓

1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:21:34	n/a - 00:45:00	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	27.07.2024 21:36:53	28.07.2024 9:18:11	11:19:44

Process Run Record Summary

Run ID 315303

2.Vessel Processing

Equipment: **VB Chamber 22** Config. Rev.: **4**
 Date Started: **28.07.2024 9:18:11** Date Completed: **28.07.2024 19:38:06** Duration: **10:19:55**

2.1.Start-up Phase

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Hi	Final - P3	48,6 °C	48,0 - 54,0 °C	✓
TE-CH-Lo	Final - P3	48,6 °C	48,0 - 54,0 °C	✓

2.2.Vacuum

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:13:09	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:13:09	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,4 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	22,0 kPa	12,0 - 32,0 kPa	✓

2.3.Leak Check

Phase No. 3

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:05:01	00:01:00 - 00:20:00	✓
Total Phase Time	Final - P11	00:05:01	00:01:00 - 00:20:00	✓
TE-CH-Lo	Min - P3	49,4 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,9 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	22,0 kPa	12,0 - 33,0 kPa	✓
PCurr	Max - P14	22,6 kPa	12,0 - 33,0 kPa	✓

2.4.Vacuum

Phase No. 4

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:22	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:22	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	49,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,0 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	22,0 kPa	21,0 - 22,2 kPa	✓

2.5.Steam Inject by Pressure

Phase No. 5

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:03:45	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:03:45	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	49,9 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,2 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,1 kPa	23,0 - 26,6 kPa	✓

Process Run Record **Summary**

Run ID 315303

Stage » Vessel Processing**2.6. Conditioning Dwell by Pressure**

Phase No. 6

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	01:25:01	01:10:00 - 01:40:00	✓
Total Phase Time	Final - P11	01:25:01	01:10:00 - 01:40:00	✓
TE-CH-Lo	Min - P3	50,2 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,0 °C	45,0 - 55,0 °C	✓
PCurr	Min - P14	23,0 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	23,6 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	58,9 %	N/A - N/A %	
RH Reported	Max - P22	80,5 %	N/A - N/A %	

2.7. Vacuum

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:41	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:41	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	50,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,6 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	22,0 kPa	21,0 - 22,2 kPa	✓

2.8. EO Inject by Pressure

Phase No. 8

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	01:03:28	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:03:28	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	50,5 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,3 °C	46,0 - 54,0 °C	✓
PCurr	Final - P1028	215,0 kPa	n/a - N/A kPa	
PCurr	Final - P14	215,0 kPa	200,0 - 225,0 kPa	✓
EO Conc. Reported	Final - P33	436,8 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	478,2 mg/l	N/A - N/A mg/l	

Process Run Record Summary

Run ID 315303

Stage » Vessel Processing**2.9.Super-Atmospheric EO Dwell**

Phase No. 9

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	06:00:01	05:55:00 - 07:00:00	✓
Total Phase Time	Final - P11	06:00:01	05:55:00 - 07:00:00	✓
TE-CH-Lo	Min - P3	49,7 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	50,7 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	207,3 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	207,3 kPa	N/A - N/A kPa	
PCurr	Max - P1028	215,0 kPa	N/A - N/A kPa	
PCurr	Max - P14	215,0 kPa	200,0 - 225,0 kPa	✓
RH Reported	Min - P22	0,0 %	N/A - N/A %	
RH Reported	Max - P22	0,0 %	N/A - N/A %	
EO Conc. Reported	Min - P33	296,8 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	436,8 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	478,2 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	479,6 mg/l	N/A - N/A mg/l	

2.10.Vacuum

Phase No. 10

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:22:24	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:22:24	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,2 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	26,0 kPa	16,0 - 36,0 kPa	✓

2.11.Air Inbleed

Phase No. 11

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:23	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:23	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,9 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

2.12.Vacuum

Phase No. 12

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:09	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:09	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	48,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,8 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

Process Run Record Summary

Run ID 315303

Stage » Vessel Processing**2.13. Air Inbleed**

Phase No. 13

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:20	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:20	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,5 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

2.14. Vacuum

Phase No. 14

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:08	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:08	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	48,8 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,5 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

2.15. Air Inbleed

Phase No. 15

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:15	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:15	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,2 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

2.16. Vacuum

Phase No. 16

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:08	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:08	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	49,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,2 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

2.17. Air Inbleed

Phase No. 17

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:16	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:16	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,6 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

Process Run Record **Summary**

Run ID 315303

Stage » Vessel Processing**2.18.End Phase**

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:19	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:00:19	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	51,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,6 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	93,0 kPa	90,0 - 103,0 kPa	✓
PCurr	Max - P14	93,0 kPa	90,0 - 103,0 kPa	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
18	0	28.07.2024 9:18:11	28.07.2024 19:38:06	10:19:55

Minimum Load Temperature before PRECOND: $\geq 10,8^{\circ}\text{C}$ value: $20,6^{\circ}\text{C}$

SIADTOX 15% - specification: N/A value: 119,9 kg

CYLINDER NR.

1. 3861
2. 6992
3. 7001
4. 48289

CONFORMING

Krezek
, Ales

Digitally signed
 by Krezek, Ales
 Date: 2024.07.29
 17:27:28 +02'00'

All dates are expressed in the timezone:

(UTC+01:00) Praha, Bratislava, Budapešť, E

✓ = Pass ✗ = Fail



**U.S. FOOD & DRUG
ADMINISTRATION**

REGISTRATION NUMBER: 2816279330

STIRILAB s.r.o. a *dominique Dutscher company*

Textilná 23

034 01

Ružomberok

VAT No. SK2021729545

Tel +421 44 432 27 20 Fax +421 44 432 27 17

www.stirilab.com, email ekonom@stirilab.com

IBAN : SK 311111 000000 102498 0028, SWIFT : UNCRSKBX



Transport Document

202403646

CUSTOMER

STERIS AST CZ s.r.o.

Průmyslová zóna Košíkov 80

595 01 Velká Bíteš, ČR

SHIP TO

STERIS AST CZ s.r.o.

Průmyslová zóna Košíkov 80

59501 Velká Bíteš Česká republika

CUST. NO.	VAT CODE	DATE	TD NUMBER	ISSUED BY	PAGE
	CZ27159621	25.07.2024	202403646		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
BSC740 order	Fertility collector lotto 24P2004308	40 exp 31.07.2028	40,000	25,00
BSV120 order	ANSA 10 uL, PP, peel pack 20 pcs,sterile lotto 24P2003406	10000 exp 31.07.2028	1 000,000	1 000,00
BSV1201 order	ANSA 10 uL, sterile lotto 24P2003704	2100 exp 31.07.2028	2 100,000	12,00
BSV1205 order	Anse jednorázové, 10uL lotto 24P2003203	4000 exp 31.07.2028	1 000,000	28,00
BSV121 order	ANSA 1 uL, PP, peel pack 20 pcs,sterile lotto 24P2003006	10000 exp 30.06.2028	1 000,000	500,00
BSV121 order	ANSA 1 uL, PP, peel pack 20 pcs,sterile lotto 24P2003007	10000 exp 31.07.2028	1 000,000	1 520,00
BSV1211 order	ANSA 1 uL, PP,peel pack 1 pcs, sterile lotto 24P2003603	0 exp 30.06.2028	2 100,000	6,00
BSV1215 order	ANSA 1 uL, PP,peel pack 5 pcs, sterile lotto 24P2003102	0 exp 30.06.2028	1 000,000	16,00

**ACCEPTANCE
VERIFICATION**

26.7.2024