

Certificate of Analysis



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

SVK
03401

Job No: BI-CZE-VEL-202403435
Report Number: 139066
Date Issued: 03-Jan-2025
Page 1 of 1

Purchase Order No: 202405807
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 : LWI-LAB002
Customer Protocol: STIRILAB 03 EQ-15%

Date Sample(s) Received: 19-Dec-2024
Date On Test: 19-Dec-2024

Analytical Results

Label ID / Designation: 202405807
Lot / Sterilization Batch: 22A241218

Microbiology

Biological Indicators

Result

BI Lot Number	488
Number of samples	28
Positive Control Check 7	Positive
Number of positives	0
Negative Controls	Negative
Time on test	19/DEC/24 09:40:27
Time off Test	27/DEC/24 09:11:16

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:

Eva Tomkova

Laboratory Operation Manager

Authorisation Date: 03-January-2025

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

Velká Biteš

595 01

STERIS: Certificate Of Processing

Prepared **STIRILAB**
For
Ethylene Oxide Run ID **2002-4884**

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202405807	18

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

Other Information

Sterilization Batch Number 22A241218

Customer Specification ID: 37

Signature Manifest

Reviewed and E-Signed By: **Miroslava Hrenakova (Quality Analyst)**

DateTime Esigned 19-Dec-2024 8:11 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, 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 ***

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:	317924	Pallet Count:	18	Batch No.:	22A241218
Customer:	routine_STIRILAB 03 EQ-15%	Checksum:	-14460	Method:	STIRILAB 03 EQ-15%
Specification:	1.4				

1.Preconditioning

Equipment:	VB Precond G	Config. Rev.:	Pending		
Date Started:	17.12.2024 18:47:15	Date Completed:	18.12.2024 7:04:41	Duration:	12:17:26

1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	12:17:26	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	12:00:00	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	47,5 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	51,6 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	48,4 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	62,5 %	45,0 - 95,0 %	✓

1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:17:20	n/a - 00:45:00	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	17.12.2024 18:47:15	18.12.2024 7:22:01	12:17:26

Process Run Record Summary

Run ID 317924

2.Vessel Processing

Equipment: **VB Chamber 22** Config. Rev.: **4**
 Date Started: **18.12.2024 7:22:01** Date Completed: **18.12.2024 17:43:36** Duration: **10:21:35**

2.1.Start-up Phase

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Hi	Final - P3	49,0 °C	48,0 - 54,0 °C	✓
TE-CH-Lo	Final - P3	48,9 °C	48,0 - 54,0 °C	✓

2.2.Vacuum

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:13:05	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:13:05	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,4 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,0 °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	48,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,3 °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	00:00:20	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:20	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	49,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,3 °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	00:03:57	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:03:57	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	49,3 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,1 kPa	23,0 - 26,6 kPa	✓

Process Run Record Summary

Run ID 317924

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	49,5 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,2 °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	56,6 %	N/A - N/A %	
RH Reported	Max - P22	79,3 %	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	50,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,1 °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	01:04:20	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:04:20	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	50,1 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,3 °C	46,0 - 54,0 °C	✓
PCurr	Final - P1028	214,9 kPa	n/a - N/A kPa	
PCurr	Final - P14	214,9 kPa	200,0 - 225,0 kPa	✓
EO Conc. Reported	Final - P33	400,5 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	474,2 mg/l	N/A - N/A mg/l	

Process Run Record Summary

Run ID 317924

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	49,4 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	50,6 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	209,8 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	209,8 kPa	N/A - N/A kPa	
PCurr	Max - P1028	214,9 kPa	N/A - N/A kPa	
PCurr	Max - P14	214,9 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	289,2 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	403,5 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	474,2 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	475,9 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	00:23:05	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:23:05	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,3 °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	00:07:19	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:19	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,8 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,1 kPa	90,0 - 103,0 kPa	✓

2.12. Vacuum

Phase No. 12

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:07	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:07	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	48,4 °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 317924

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

Phase No. 13

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:13	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:13	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,5 °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	00:12:07	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:07	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	00:07:12	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:12	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,8 °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	49,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,8 °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	00:07:19	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:19	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,4 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,3 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

Process Run Record Summary

Run ID 317924

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

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:34	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:00:34	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	51,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,3 °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	18.12.2024 7:22:01	18.12.2024 17:43:36	10:21:35

Process Run Record Summary

Run ID 317924

3.Aeration

Equipment: **VB Aeration 01** Config. Rev.: **Pending**
 Date Started: **18.12.2024 18:04:22** Date Completed: **19.12.2024 5:12:48** Duration: **11:08:26**

3.1.Aeration

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:08:26	00:00:00 - 7d 00:00:00	✓
Time-InSpec	Final - P104	11:05:00	00:00:00 - 7d 00:00:00	✓
TE-Min-In-Spec	Min - P101	44,6 °C	41,0 - 51,0 °C	✓
TempAve	Max - P101	48,8 °C	41,0 - 51,0 °C	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
1	0	18.12.2024 18:04:22	19.12.2024 5:12:48	11:08:26

Minimum Load Temperature before PRECOND: $\geq 10,8$ ° C value: 19,8 ° C
 SIADTOX 15% - specification: N/A value: 120,6 kg
 CYLINDER NR.

1. 6640
2. 8329
3. 7443
4. 9315

CONFORMING

Vrbka, Digitálně podepsal
 Vojtech Vrbka, Vojtech
 Datum: 2024.12.19
 06:28:24 +01'00'

All dates are expressed in the timezone:

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

✓ = Pass ✗ = Fail



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



202405807

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
	CZZ7159621	16.12.2024	202405807		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
7 696 430 order	Microloops 10 ul sterile lotto 24P2018802	10000 exp 31.12.2028	1 000,000	300,00
7 696 431 order	Microloops 1 ul sterile lotto 24P2018502	10000 exp 31.12.2028	1 000,000	60,00
BSC740 order	Fertility collector lotto 24P2004312	40 exp 30.11.2028	40,000	64,00
BSV120 order	ANSA 10 uL, PP, peel pack 20 pcs,sterile lotto 24P2003410	10000 exp 30.11.2028	1 000,000	20,00
BSV120 order	ANSA 10 uL, PP, peel pack 20 pcs,sterile lotto 24P2003411	10000 exp 31.12.2028	1 000,000	1 130,00
BSV121 order	ANSA 1 uL, PP, peel pack 20 pcs,sterile lotto 24P2003011	10000 exp 30.11.2028	1 000,000	1 240,00
BSV1211 order	ANSA 1 uL, PP,peel pack 1 pcs, sterile lotto 24P2003607	0 exp 31.12.2028	2 100,000	5,00



Transport Document

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

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

CUST. NO.	VAT CODE	DATE	TD NUMBER	ISSUED BY	PAGE
	CZ27159821	16.12.2024	202405807		2 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
------	-------------	-------------	----	----------

SHIPPING BY

EXW

ISSUED BY:

Božeková

TRANSPORT

SALE

TRANSPORT START DATE

16.12.2024

DELIVERY TERM

EXW

BOXES

344

PALLETS

18

GROSS WEIGHT KG

2 781,25

NETTO WEIGHT

2 547,26

VOLUME m3

20,15

DRIVER'S SIGNATURE

ANNOTATIONS

RECIPIENT'S SIGNATURE

Any complaint must be made within 8 days after goods receipt. Goods are considered of customer property only after full payment receipt. Any disputes between the are subject to the exclusive jurisdiction of the courts of Slovak republic

ACCEPTANCE
VERIFICATION

17.12.2024