

Certificate of Analysis



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

SVK
03401

Job No: BI-CZE-VEL-202500773
Report Number: 149210
Date Issued: 10-Mar-2025
Page 1 of 1

Purchase Order No: 202500902
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 : LWM-LAB002
Customer Protocol: STIRILAB 03 EQ-15%

Date Sample(s) Received: 03-Mar-2025
Date On Test: 03-Mar-2025

Analytical Results

Label ID / Designation: 202500902

Lot / Sterilization Batch: 22A250301

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	03-03-2025 11:00:45
Time off Test	10-03-2025 11:00:58

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: 10-March-2025

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

Velká Bíteš

STERIS: Certificate Of Processing

Prepared STIRILAB SRO
For
Ethylene Oxide Run ID 2002-5637

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202500902	18

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

Other Information

Sterilization Batch Number 22A250301

Customer Specification ID: 55

Signature Manifest

Reviewed and E-Signed By: **Martin Vanek (Quality Engineer)**

Date/Time Signed 03-Mar-2025 11:02 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:	318828	Pallet Count:	18	Batch No.:	22A250301
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:	28.02.2025 17:58:38	Date Completed:	01.03.2025 5:22:24
		Duration:	11:23:46

1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:23:46	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	11:05:01	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	48,8 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	52,4 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	53,3 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	62,8 %	45,0 - 95,0 %	✓

1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:16:05	n/a - 00:45:00	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	28.02.2025 17:58:38	01.03.2025 5:38:29	11:23:46

Process Run Record Summary

Run ID 318828

2.Vessel Processing

Equipment: VB Chamber 22

Config. Rev.: 5

Date Started: 01.03.2025 5:38:29

Date Completed: 01.03.2025 17:04:55

Duration: 11:26:26

2.1.Start-up Phase

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Hi	Final - P3	49,7 °C	48,0 - 54,0 °C	✓
TE-CH-Lo	Final - P3	49,7 °C	48,0 - 54,0 °C	✓

2.2.Vacuum

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:33	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:12:33	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	49,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,7 °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	22,7 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	49,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,9 °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	00:03:59	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:03:59	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	49,9 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,1 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,1 kPa	23,0 - 26,6 kPa	✓

Process Run Record Summary

Run ID 318828

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	50,1 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,5 °C	45,0 - 55,0 °C	✓
PCurr	Min - P14	22,9 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	23,3 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	74,1 %	N/A - N/A %	
RH Reported	Max - P22	92,6 %	N/A - N/A %	

2.7. Vacuum

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:31	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:31	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	50,1 °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	01:03:55	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:03:55	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	50,1 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	50,9 °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	414,2 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 318828

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	50,4 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	208,6 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	208,6 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	304,4 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	414,3 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	475,2 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	00:20:59	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:20:59	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,0 °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	00:07:26	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:26	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,8 °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	00:12:10	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:10	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	48,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,9 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

Process Run Record Summary

Run ID 318828

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

Phase No. 13

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	49,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,0 °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	00:12:09	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	48,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,0 °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	00:07:19	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	49,8 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,9 °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	00:12:09	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	49,8 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,8 °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	50,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	52,3 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

Process Run Record Summary

Run ID 318828

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

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	01:08:10	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	01:08:10	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	50,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	52,3 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	93,0 kPa	90,0 - 103,0 kPa	✓
PCurr	Max - P14	94,6 kPa	90,0 - 103,0 kPa	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
18	0	01.03.2025 5:38:29	01.03.2025 17:04:55	11:26:26

3.Aeration

Equipment:	VB Aeration 09	Config. Rev.:	Pending
Date Started:	01.03.2025 18:09:32	Date Completed:	01.03.2025 22:33:04
		Duration:	04:23:32

3.1.Aeration

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	04:23:32	00:00:00 - 7d 00:00:00	✓
Time-InSpec	Final - P104	04:20:00	00:00:00 - 7d 00:00:00	✓
TE-Min-In-Spec	Min - P101	44,9 °C	41,0 - 51,0 °C	✓
TempAve	Max - P101	48,3 °C	41,0 - 51,0 °C	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
1	0	01.03.2025 18:09:32	01.03.2025 22:33:04	04:23:32

Minimum Load Temperature before PRECOND: ≥ 10,8 ° C value: 18,6 ° C
SIADTOX 15% - specification: N/A value: 120.3 kg
CYLINDER NR.
1. 9316
2. 6636
3. 48145
4. 681

CONFORMING

Malina, Milan

Digitally signed by Malina, Milan
Date: 2025.03.03 07:37:23
+01'00'



Transport Document



202500902

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

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	25.02.2025	202500902		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
BSC740	Fertility collector	40	40,000	1,00
order	lotto 24P2004311	exp 31.10.2028		
BSC740	Fertility collector	40	40,000	32,00
order	lotto 25P2005600	exp 31.01.2029		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	1 400,00
order	lotto 25P2002801	exp 28.02.2029		
BSV1200	ANSA 10 uL, PP, peel pack 10 pcs,sterile	12000	1 000,000	216,00
order	lotto 25P2002501	exp 28.02.2029		
BSV1201	ANSA 10 uL, sterile	2100	2 100,000	12,00
order	lotto 25P2002901	exp 28.02.2029		
BSV1205	Anse jednorázové, 10ul	4000	1 000,000	24,00
order	lotto 25P2002401	exp 28.02.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	510,00
order	lotto 25P2002200	exp 31.01.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	710,00
order	lotto 25P2002201	exp 28.02.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	210,00
order	lotto 25P2002201	exp 28.02.2029		

ACCEPTANCE
VERIFICATIONSTERIS AST CZ s.r.o. ®
Průmyslová zóna Košíkov 80
595 01 Velká Bíteš
IČ: 271 59 621, DIČ: CZ2715962127.2.25
910



U.S. FOOD & DRUG
ADMINISTRATION

STIRILAB s.r.o. a dominique Dutscher company

Textilná 23

034 01

Ružomberok

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

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IBAN : SK 311111 000000 102498 0028, SWIFT : UNCRSKBX

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

CUST. NO.	VAT CODE	DATE	TD NUMBER	ISSUED BY	PAGE
	CZ27159621	25.02.2025	202500902		2 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
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SHIPPING BY

EXW

ISSUED BY:

Božeková

TRANSPORT

SALE

TRANSPORT START DATE

25.02.2025

DELIVERY TERM

EXW

BOXES

352

PALLETS

18

GROSS WEIGHT KG

2 753,16

NETTO WEIGHT

2 533,40

VOLUME m3

19,11

DRIVER'S SIGNATURE

ANNOTATIONS

RECIPIENT'S SIGNATURE

Any compliant 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