

Certificate of Analysis



Customer: Stirilab s.r.o.
Address: Textilná 23
Ružomberok
SVK
03401

Job No: BI-CZE-VEL-202502711
Report Number: 170767
Date Issued: 14-Jul-2025
Page 1 of 1

Purchase Order No: 202502994
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 : LVM-LAB002
Customer Protocol: STIRILAB 03 EQ-15%

Date Sample(s) Received: 07-Jul-2025
Date On Test: 07-Jul-2025

Analytical Results

Label ID / Designation: 202502994

Lot / Sterilization Batch: 22A250706

Microbiology

Result

Biological Indicators

BI Lot Number	494
Number of samples	28
Positive Control Check 7	Positive
Number of positives	0
Negative Controls	Negative
Time on test	07/JUL/2025 10:30
Time off Test	14/JUL/2025 11:03

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

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Released by:

Eva Tomkova

Laboratory Operation Manager

Authorisation Date: 14-July-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 2002-7575

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202502994	18

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

Other Information

Sterilization Batch Number 22A250706

Customer Specification ID: 55

Signature Manifest

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

Date/Time E-signed 07-Jul-2025 8:15 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:	320894	Pallet Count:	18	Batch No.:	22A250706
Customer:	routine_STIRILAB 03 EQ-15%	Checksum:	-1107	Method:	STIRILAB 03 EQ-15%
Specification:	1.6				

1.Preconditioning

Equipment:	VB Precond G	Config. Rev.:	Pending
Date Started:	05.07.2025 17:23:51	Date Completed:	06.07.2025 6:02:46
		Duration:	12:38:55

1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	12:38:55	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	12:25:01	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	49,1 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	52,3 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	53,0 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	62,3 %	45,0 - 95,0 %	✓

1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:11:23	n/a - 00:45:00	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	05.07.2025 17:23:51	06.07.2025 6:14:09	12:38:55

Process Run Record Summary

Run ID 320894

2.Vessel Processing

Equipment: VB Chamber 22 Config. Rev.: 6
 Date Started: 06.07.2025 6:14:09 Date Completed: 06.07.2025 17:09:10 Duration: 10:55:01

2.1.Start-up Phase

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Lo	Final - P3	48,5 °C	48,0 - 54,0 °C	✓
TE-CH-Hi	Final - P3	48,5 °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	48,3 °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	49,6 °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	00:00:21	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:21	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	49,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,6 °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	00:03:44	00:01:00 - 00:20:00	✓
Total Phase Time	Final - P11	00:03:44	00:01:00 - 00:20:00	✓
TE-CH-Lo	Min - P3	49,6 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,9 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,2 kPa	23,0 - 26,6 kPa	✓

Process Run Record Summary

Run ID 320894

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 - 01:32:00	✓
Total Phase Time	Final - P11	01:25:01	01:10:00 - 01:32:00	✓
TE-CH-Lo	Min - P3	49,9 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,6 °C	45,0 - 55,0 °C	✓
PCurr	Min - P14	23,1 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	24,0 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	72,4 %	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	00:00:47	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:47	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	50,4 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,4 °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	01:03:27	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:03:27	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	50,4 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,5 °C	46,0 - 54,0 °C	✓
PCurr	Final - P14	214,9 kPa	200,0 - 225,0 kPa	✓
PCurr	Final - P1028	214,9 kPa	n/a - N/A kPa	
EO Conc. Reported	Final - P33	452,1 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	478,4 mg/l	N/A - N/A mg/l	

Process Run Record Summary

Run ID 320894

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	51,0 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	210,4 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	210,4 kPa	N/A - N/A kPa	
PCurr	Max - P14	215,0 kPa	200,0 - 225,0 kPa	✓
PCurr	Max - P1028	215,0 kPa	N/A - N/A 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	319,6 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	452,1 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	478,4 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	480,3 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	00:21:55	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:21:55	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,1 °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	00:07:24	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:24	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,3 °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	00:12:08	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	48,4 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,3 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

Process Run Record Summary

Run ID 320894

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

Phase No. 13

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:18	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:18	00:03:00 - 00:17:00	✓
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	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	48,6 °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	✓

2.15.Air Inbleed

Phase No. 15

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:18	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:18	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,6 °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	49,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,6 °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	00:07:18	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:18	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,0 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

Stage » Vessel Processing

2.18.End Phase

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:35:52	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:35:52	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	50,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,1 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	93,0 kPa	90,0 - 103,0 kPa	✓
PCurr	Max - P14	94,0 kPa	90,0 - 103,0 kPa	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
18	0	06.07.2025 6:14:09	06.07.2025 17:09:10	10:55:01

3.Aeration

Equipment:	VB Aeration 35	Config. Rev.:	Pending
Date Started:	06.07.2025 19:33:38	Date Completed:	06.07.2025 22:16:50
		Duration:	02:43:12

3.1.Aeration

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	02:43:12	00:00:00 - 7d 00:00:00	✓
Time-InSpec	Final - P104	02:40:00	00:00:00 - 7d 00:00:00	✓
TE-Min-In-Spec	Min - P101	41,0 °C	41,0 - 51,0 °C	✓
TempAve	Max - P101	47,4 °C	41,0 - 51,0 °C	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
1	0	06.07.2025 19:33:38	06.07.2025 22:16:50	02:43:12

Minimum Load Temperature before PRECOND: ≥ 10,8 ° C value: 22,7 ° C
SIADTOX 15% - specification: N/A value: 119,0 kg
CYLINDER NR.
1. 4687
2. 4898
3. 7130
4. 3251

CONFORMING

Vrbka,
Vojtech

Digitálně podepsal
Vrbka, Vojtech
Datum: 2025.07.07
06:43:37 +02'00'



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

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

595 01 Velká Bíteš Česká republika

CUST. NO.	VAT CODE	DATE	TD NUMBER	ISSUED BY	PAGE
	CZ27156621	02.07.2025	202502994		2 to 2

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

**ACCEPTANCE
VERIFICATION**

SHIPPING BY

EXW

ISSUED BY:

Božeková

TRANSPORT

SALE

TRANSPORT START DATE

02.07.2025

DELIVERY TERM

EXW

BOXES

348

PALLETS

18

GROSS WEIGHT KG

2 861,11

NETTO WEIGHT

2 634,75

VOLUME m3

19,88

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



Transport Document



202502994

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

595 01 Velká Bíteš Česká republika

CUST. NO.	VAT CODE	DATE	TD NUMBER	ISSUED BY	PAGE
	CZ27159621	02.07.2025	202502994		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
BSC740	Fertility collector	40	40,000	48,00
order	lotto 25P2005604	exp 30.06.2029		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs, sterile	10000	1 000,000	10,00
order	lotto 25P2002604	exp 30.04.2029		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs, sterile	10000	1 000,000	200,00
order	lotto 25P2002606	exp 30.06.2029		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs, sterile	10000	1 000,000	1 400,00
order	lotto 25P2002607	exp 30.06.2029		
BSV1200	ANSA 10 uL, PP, peel pack 10 pcs, sterile	12000	1 000,000	72,00
order	lotto 25P2002502	exp 30.06.2029		
BSV1201	ANSA 10 uL, sterile	2100	2 100,000	6,00
order	lotto 25P2002904	exp 30.06.2029		
BSV1205	Anse jednorázové, 10uL	4000	1 000,000	16,00
order	lotto 25P2002402	exp 30.06.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs, sterile	10000	1 000,000	20,00
order	lotto 25P2002204	exp 30.04.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs, sterile	10000	1 000,000	980,00
order	lotto 25P2002205	exp 30.06.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs, sterile	10000	1 000,000	50,00
order	lotto 25P2029001	exp 31.05.2029		
BSV1210	Anse single-use, volume 1 uL	12000	1 000,000	156,00
order	lotto 25P2002703	exp 31.07.2029		
BSV1211	ANSA 1 uL, PP, peel pack 1 pcs, sterile	0	2 100,000	2,00
order	lotto 25P2002802	exp 30.06.2029		
BSV1215	ANSA 1 uL, PP, peel pack 5 pcs, sterile	0	1 000,000	12,00
order	lotto 25P2002302	exp 30.06.2029		

STERIS AST CZ s.r.o. ©
Průmyslová zóna Košíkov 80
595 01 Velká Bíteš
IČ: 271 59 621, DIČ: CZ27159621

ACCEPTANCE
VERIFICATION

4.7.2025 10⁰⁰ 15