

Certificate of Analysis



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

SVK
03401

Job No: BI-CZE-VEL-202502263
Report Number: 165842
Date Issued: 16-Jun-2025
Page 1 of 1

Purchase Order No: 202502525
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: 09-Jun-2025
Date On Test: 09-Jun-2025

Analytical Results

Label ID / Designation: 202502525

Lot / Sterilization Batch: 22250608

Microbiology

Result

Biological Indicators

BI Lot Number	489
Number of samples	28
Positive Control Check 7	Positive
Number of positives	0
Negative Controls	Negative
Time on test	09-06-2025 10:40:00
Time off Test	16-06-2025 11:00:29

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: 16-June-2025

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

Velká Bíteš

595 01

STERIS: Certificate Of Processing

Prepared STIRILAB SRO
For
Ethylene Oxide Run ID 2002-7120

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202502525	18

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

Other Information

Sterilization Batch Number 22250608

Customer Specification ID: 55

Signature Manifest

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

Date/Time E-signed 09-Jun-2025 7:52 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 ***

Document ID: 24808

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:	320418	Pallet Count:	18	Batch No.:	22250608
Customer:	routine_STIRILAB 03 EQ-15%	Checksum:	29074	Method:	STIRILAB 03 EQ-15%
Specification:	1.5				

1.Preconditioning

Equipment:	VB Precond G	Config. Rev.:	Pending
Date Started:	07.06.2025 5:33:04	Date Completed:	07.06.2025 17:30:58
		Duration:	11:57:54

1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:57:54	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	11:50:00	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	46,6 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	52,0 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	48,5 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	64,1 %	45,0 - 95,0 %	✓

1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:11:28	n/a - 00:45:00	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	07.06.2025 5:33:04	07.06.2025 17:42:26	11:57:54

Process Run Record Summary

Run ID 320418

2.Vessel Processing

Equipment: VB Chamber 22

Config. Rev.: 6

Date Started: 07.06.2025 17:42:26

Date Completed: 08.06.2025 4:45:05

Duration: 11:02:39

2.1.Start-up Phase

Phase No. 1

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

2.2.Vacuum

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:13:00	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:13:00	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °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	50,0 °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	00:00:23	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:23	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	00:03:22	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:03:22	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 320418

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	50,6 °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	76,0 %	N/A - N/A %	
RH Reported	Max - P22	94,1 %	N/A - N/A %	

2.7. Vacuum

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:39	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:39	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	50,3 °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	01:03:10	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:03:10	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	50,3 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,4 °C	46,0 - 54,0 °C	✓
PCurr	Final - P14	215,0 kPa	200,0 - 225,0 kPa	✓
PCurr	Final - P1028	215,0 kPa	n/a - N/A kPa	
EO Conc. Reported	Final - P33	447,3 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	477,9 mg/l	N/A - N/A mg/l	

Process Run Record Summary

Run ID 320418

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	49,6 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	50,9 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	209,0 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	209,0 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	320,0 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	448,7 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	477,9 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	479,7 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	00:21:25	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:21:25	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	47,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,9 °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	48,4 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,1 °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	47,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,1 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

Process Run Record Summary

Run ID 320418

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	48,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,1 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	48,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °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	00:07:20	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	48,8 °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	✓

2.16. 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	48,8 °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	✓

2.17. 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	49,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,3 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

Process Run Record

Summary

Run ID320418

Stage » Vessel Processing

2.18.End Phase

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:44:44	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:44:44	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	49,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,4 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	93,0 kPa	90,0 - 103,0 kPa	✓
PCurr	Max - P14	94,3 kPa	90,0 - 103,0 kPa	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
18	0	07.06.2025 17:42:26	08.06.2025 4:45:05	11:02:39

3.Aeration

Equipment:	VB Aeration 07	Config. Rev.:	Pending
Date Started:	08.06.2025 8:48:30	Date Completed:	08.06.2025 9:10:45
		Duration:	00:22:15

3.1.Aeration

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	00:22:15	00:00:00 - 7d 00:00:00	✓
Time-InSpec	Final - P104	00:15:00	00:00:00 - 7d 00:00:00	✓
TE-Min-In-Spec	Min - P101	42,5 °C	41,0 - 51,0 °C	✓
TempAve	Max - P101	46,6 °C	41,0 - 51,0 °C	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
1	0	08.06.2025 8:48:30	08.06.2025 9:10:45	00:22:15

Minimum Load Temperature before PRECOND: ≥ 10,8 ° C value: 22,1 ° C
SIADTOX 15% - specification: N/A value: 119,7 kg
CYLINDER NR.
1. 2216
2. 45326
3. 11623
4. 5118

CONFORMING

Vrbka,
Vojtech

Digitálně
podepsal Vrbka,
Vojtech
Datum: 2025.06.09
06:51:45 +02'00'



U.S. FOOD & DRUG
ADMINISTRATION

202502525

Transport Document



202502525

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

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
	CZ27159621	04.06.2025	202502525		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
1131403	Anse single-use, packed in envelopes	10000	1 000,000	400,00
order	lotto 25P2029800	exp 31.05.2029		
1131404	Anse single-use, 10 ul, in envelopes	10000	1 000,000	100,00
order	lotto 25P2029900	exp 31.05.2029		
7 696 430	Microloops 10 ul sterile	10000	1 000,000	400,00
order	lotto 25P2030100	exp 31.05.2029		
7 696 431	Microloops 1 ul sterile	10000	1 000,000	310,00
order	lotto 25P2030000	exp 31.05.2029		
BSC740	Fertility collector	40	40,000	25,00
order	lotto 25P2005603	exp 30.04.2029		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	20,00
order	lotto 25P2002602	exp 31.03.2029		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	410,00
order	lotto 25P2002604	exp 30.04.2029		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	550,00
order	lotto 25P2002605	exp 31.05.2029		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	250,00
order	lotto 25P2002606	exp 30.06.2029		
BSV1200	ANSA 10 uL, PP, peel pack 10 pcs,sterile	12000	1 000,000	60,00
order	lotto 25P2029300	exp 31.05.2029		
BSV1201	ANSA 10 ul , sterile	2100	2 100,000	4,00
order	lotto 25P2002903	exp 31.05.2029		
BSV1201	ANSA 10 ul , sterile	2100	2 100,000	3,00
order	lotto 25P2029700	exp 31.05.2029		
BSV1205	Anse jednorázové, 10ul	4000	1 000,000	16,00
order	lotto 25P2029200	exp 31.05.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	70,00
order	lotto 25P2002204	exp 30.04.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	150,00
order	lotto 25P2029000	exp 30.04.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	450,00
order	lotto 25P2029001	exp 31.05.2029		
BSV1210	Anse single-use, volume 1 ul	12000	1 000,000	12,00
order	lotto 25P2002702	exp 31.05.2029		
BSV1210	Anse single-use, volume 1 ul	12000	1 000,000	36,00
order	lotto 25P2029500	exp 31.05.2029		



U.S. FOOD & DRUG
ADMINISTRATION

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
	CZ27159621	04.06.2025	202502525		2 to 2

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

SHIPPING BY

EXW

ISSUED BY:

Božeková

TRANSPORT

SALE

TRANSPORT START DATE

04.06.2025

DELIVERY TERM

EXW

BOXES

356

PALLETS

18

GROSS WEIGHT KG

3 088,84

NETTO WEIGHT

2 859,76

VOLUME m3

20,46

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

ACCEPTANCE
VERIFICATION