Certificate of Analysis

STERIS

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

Final Report

Job No:	**BI-CZE-VEL-202501763**
Report Number:	160407
Date Issued:	14-May-2025
	Page 1 of 1

Purchase Order No:	202501904
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:	07-May-2025
Date On Test:	07-May-2025

Analytical Results

Label ID / Designation: 202501904

Lot / Sterilization Batch: 22250507

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	07-05-2025 10:35:33
Time off Test	14-05-2025 10:39:14

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

Eva Tomkova — **Laboratory Operation Manager**

Authorisation Date: 14-May-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 For **STIRILAB SRO**
Ethylene Oxide Run ID 2002-6613

Product Code	Lot Number	Quantity (PL)
STIRILAB 03 EQ-15%	202501904	18

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

Other Information

Sterilization Batch Number 22250507

Customer Specification ID: 55

Signature Manifest

Reviewed and E-Signed By: **Martin Vanek (Quality Engineer)**
DateTime Esigned 07-May-2025 8:43 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:	**319904**	Pallet Count:	**18**		
Customer:	**routine_STIRILAB 03 EQ-15%**			Batch No.:	**22250507**
Specification:	**1.4**	Checksum:	**-14460**	Method:	**STIRILAB 03 EQ-15%**

1.Preconditioning

Equipment:	**VB Precond G**			Config. Rev.:	**Pending**
Date Started:	**06.05.2025 5:33:39**	Date Completed:	**06.05.2025 17:11:36**	Duration:	**11:37:57**

1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:37:57	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	11:20:00	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	46,5 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	51,9 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	52,5 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	63,0 %	45,0 - 95,0 %	✓

1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:17:37	n/a - 00:45:00	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	**0**	06.05.2025 5:33:39	06.05.2025 17:29:13	11:37:57

Process Run Record **Summary** Run ID 319904

2.Vessel Processing

Equipment: **VB Chamber 22** Config. Rev.: **6**
Date Started: **06.05.2025 17:29:13** Date Completed: **07.05.2025 4:41:37** Duration: **11:12:24**

2.1.Start-up Phase

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Lo	Final - P3	48,3 °C	48,0 - 54,0 °C	✓
TE-CH-Hi	Final - P3	48,3 °C	48,0 - 54,0 °C	✓

2.2.Vacuum

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:13:17	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:13:17	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	47,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	48,5 °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	48,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,1 °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	00:00:22	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	49,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,1 °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	00:04:09	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:04:09	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	49,1 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,3 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,1 kPa	23,0 - 26,6 kPa	✓

Process Run Record **Summary** Run ID 319904

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	49,3 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,1 °C	45,0 - 55,0 °C	✓
PCurr	Min - P14	23,0 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	23,5 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	73,0 %	N/A - N/A %	
RH Reported	Max - P22	91,8 %	N/A - N/A %	

2.7.Vacuum

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:36	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:36	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	01:03:27	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	50,0 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,0 °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	397,4 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	474,8 mg/l	N/A - N/A mg/l	

Process Run Record **Summary** Run ID 319904

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	50,7 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	209,4 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	209,4 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	281,8 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	397,4 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	474,8 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	476,5 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	00:21:37	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:21:37	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	47,9 °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	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,7 °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	48,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,6 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

Process Run Record **Summary** Run ID 319904

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	48,6 °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	✓

2.14.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	48,7 °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	✓

2.15.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	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	48,8 °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	00:07:21	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:21	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,5 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

Process Run Record **Summary** Run ID 319904

Stage » **Vessel Processing**

2.18.End Phase

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:52:59	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:52:59	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	50,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,5 °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	06.05.2025 17:29:13	07.05.2025 4:41:37	11:12:24

Process Run Record **Summary** Run ID 319904

3.Aeration

Equipment:	**VB Aeration 04**			Config. Rev.:	**Pending**
Date Started:	**07.05.2025 5:34:00**	Date Completed:	**07.05.2025 8:20:05**	Duration:	**02:46:05**

3.1.Aeration

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	02:46:05	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	44,3 °C	41,0 - 51,0 °C	✓
TempAve	Max - P101	47,3 °C	41,0 - 51,0 °C	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
1	0	07.05.2025 5:34:00	07.05.2025 8:20:05	02:46:05

Minimum Load Temperature before PRECOND: ≥ 10,8 ° C value: 23,1 ° C
SIADTOX 15% - specification: N/A value: 120,3 kg
CYLINDER NR.
1. 6982
2. 4806
3. 61
4. 58699

CONFORMING

Malina, Milan Digitally signed by Malina, Milan
Date: 2025.05.07 08:28:24 +02'00'

All dates are expressed in the timezone: (UTC+01:00) Praha, Bratislava, Budapešť, E ✓ = Pass ✗ = Fail

Transport Document 202501904

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

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034 01
Ružomberok

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

IBAN : SK 311111 000000 102498 0028, SWIFT : UNCRSKBX

CUSTOMER

STERIS AST CZ s.r.o.

Prúmyslová zóna Košíkov 80

595 01 Velká Bíteš, ČR

SHIP TO

STERIS AST CZ s.r.o.

Prúmyslová zóna Košíkov 80

59501 Velká Bíteš Česká republika

CUST. NO.	*VAT CODE*	*DATE*	*TD NUMBER*	*ISSUED BY*	*PAGE*
	CZ27159621	30.04.2025	202501904		1 to 2

CODE	*DESCRIPTION*		*QTY per BOX*	*MU*	*QUANTITY*
7 696 430	Microloops 10 ul sterile		10000	1 000,000	340,00
order	lotto 25P2026800	exp 30.04.2029			
7 696 430	Microloops 10 ul sterile		10000	1 000,000	80,00
order	lotto 25P2026800	exp 30.04.2029			
7 696 431	Microloops 1 ul sterile		10000	1 000,000	50,00
order	lotto 25P2026700	exp 30.04.2029			
BSC740	Fertility collector		40	40,000	80,00
order	lotto 25P2005603	exp 30.04.2029			
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile		10000	1 000,000	780,00
order	lotto 25P2002602	exp 31.03.2029			
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile		10000	1 000,000	200,00
order	lotto 25P2002603	exp 31.03.2029			
BSV1201	ANSA 10 ul , sterile		2100	2 100,000	10,00
order	lotto 25P2002902	exp 30.04.2029			
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile		10000	1 000,000	950,00
order	lotto 25P2002204	exp 30.04.2029			
BSV1211	ANSA 1 uL, PP,peel pack 1 pcs, sterile		0	2 100,000	4,00
order	lotto 25P2002801	exp 30.04.2029			
BSV1216	ANSA 1 uL, PP,peel pack 5 pcs, sterile		0	1 000,000	24,00
order	lotto 25P2002301	exp 30.04.2029			

ACCEPTANCE VERIFICATION

14:30
2.5.2025
Svoja

Transport Document

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.
Prúmyslová zóna Košíkov 80
595 01 Velká Bíteš, ČR

SHIP TO
STERIS AST CZ s.r.o.
Prúmyslová zóna Košíkov 80
59501 Velká Bíteš Česká republika

CUST. NO.	VAT CODE	DATE	TD NUMBER	ISSUED BY	PAGE
	CZ27159621	30.04.2025	202501904		2 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY

SHIPPING BY	ISSUED BY:	TRANSPORT	TRANSPORT START DATE
EXW	Božeková	SALE	30.04.2025

DELIVERY TERM	BOXES	PALLETS	GROSS WEIGHT KG	NETTO WEIGHT	VOLUME m3	DRIVER'S SIGNATURE
EXW	340	18	2 560,26	2 337,89	19,42	

ANNOTATIONS

RECIPIENT'S SIGNATURE

Any compliant must by 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