

# Certificate of Analysis



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

**Job No:** BI-CZE-VEL-202500352  
**Report Number:** 144393  
**Date Issued:** 10-Feb-2025  
Final Report  
Page 1 of 1

**Purchase Order No:** 202500432  
**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:** 03-Feb-2025  
**Date On Test:** 03-Feb-2025

## Analytical Results

**Label ID / Designation:** 202500432

**Lot / Sterilization Batch:** 22A250201

**Microbiology**

**Biological Indicators**

### Result

BI Lot Number	488
Number of samples	28
Positive Control Check	7
Number of positives	0
Negative Controls	Negative
Time on test	03-02-2025 10:15:46
Time off Test	10-02-2025 10:16:51

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

**Authorisation Date:**

10-February-2025

**Laboratory Operation Manager**

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

Velká Bites

595 01

# STERIS: Certificate Of Processing

Prepared STIRILAB  
For  
Ethylene Oxide Run ID 2002-5235

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202500432	18

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

## Other Information

Sterilization Batch Number 22A250201

Customer Specification ID: 37

## Signature Manifest

Reviewed and E-Signed By: **Sarka Mejzlikova (Quality Analyst)**

DateTime Esigned 03-Feb-2025 9:15 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 \*\*\*

Document ID: 19469

# 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:	<b>318396</b>	Pallet Count:	<b>18</b>	Batch No.:	<b>22A250201</b>
Customer:	<b>routine_STIRILAB 03 EQ-15%</b>	Checksum:	<b>-14460</b>	Method:	<b>STIRILAB 03 EQ-15%</b>
Specification:	<b>1.4</b>				

## 1. Preconditioning

Equipment: **VB Precond G** Config. Rev.: **Pending**  
Date Started: **31.01.2025 17:56:39** Date Completed: **01.02.2025 5:59:32** Duration: **12:02:53**

### 1.1. Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	12:02:53	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	11:50:01	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	48,5 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	52,0 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	47,8 %	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	00:11:41	n/a - 00:45:00	✓

### Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	31.01.2025 17:56:39	01.02.2025 6:11:13	12:02:53

**Process Run Record Summary**

Run ID 318396

**2.Vessel Processing**

Equipment: **VB Chamber 22** Config. Rev.: **4**  
 Date Started: **01.02.2025 6:11:13** Date Completed: **01.02.2025 17:10:19** Duration: **10:59:06**

**2.1.Start-up Phase**

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Hi	Final - P3	48,6 °C	48,0 - 54,0 °C	✓
TE-CH-Lo	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	00:12:37	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:12:37	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	49,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °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	49,4 °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	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	00:04:00	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:04:00	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	49,4 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,7 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,1 kPa	23,0 - 26,6 kPa	✓



**Process Run Record Summary**

Run ID 318396

**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	23,1 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	23,6 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	70,9 %	N/A - N/A %	
RH Reported	Max - P22	96,3 %	N/A - N/A %	

**2.7. Vacuum**

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:36	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	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	✓

**2.8. EO Inject by Pressure**

Phase No. 8

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	01:04:55	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:04:55	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	49,9 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	50,7 °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	397,4 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	474,6 mg/l	N/A - N/A mg/l	

**Process Run Record Summary**

Run ID 318396

**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	49,5 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	50,1 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	209,7 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	209,7 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	289,2 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	398,2 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	474,6 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	475,4 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	00:22:14	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:22:14	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	47,7 °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	00:08:23	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:08:23	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,6 °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	48,2 °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 318396

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

Phase No. 13

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:16	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:16	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,2 °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	50,2 °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	49,1 °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	00:12:09	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	49,2 °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	00:07:18	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	51,1 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

**Process Run Record Summary**

Run ID 318396

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

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:37:33	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:37:33	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	50,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,0 °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	01.02.2025 6:11:13	01.02.2025 17:10:19	10:59:06



**Process Run Record Summary**

Run ID 318396

**3.Aeration**

Equipment: **VB Aeration 35** Config. Rev.: **Pending**  
 Date Started: **01.02.2025 17:36:00** Date Completed: **02.02.2025 17:12:25** Duration: **23:36:25**

**3.1.Aeration**

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	23:36:25	00:00:00 - 7d 00:00:00	✓
Time-InSpec	Final - P104	23:30:01	00:00:00 - 7d 00:00:00	✓
TE-Min-In-Spec	Min - P101	45,4 °C	41,0 - 51,0 °C	✓
TempAve	Max - P101	47,7 °C	41,0 - 51,0 °C	✓

**Stage Summary**

Steps	Deviations	Date Started	Date Ended	Total Duration:
1	0	01.02.2025 17:36:00	02.02.2025 17:12:25	23:36:25

Minimum Load Temperature before PRECOND:  $\geq 10,8$  ° C value: 23,5 ° C

SIADTOX 15% - specification: N/A value: 119,6 kg

CYLINDER NR.

1. 8487

2. 2171

3. 7338

4. 3533

**CONFORMING**

Vrbka,  
Vojtech

Digitálně podepsal  
Vrbka, Vojtech  
Datum: 2025.02.03  
06:28:49 +01'00'

All dates are expressed in the timezone:

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

✓ = Pass ✗ = Fail

**Transport Document**

202500432

**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	29.01.2025	202500432		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
BSC740 order	Fertility collector lotto 24P2004312	40 exp 30.11.2028	40,000	19,00
BSC740 order	Fertility collector lotto 24P2004313	40 exp 31.12.2028	40,000	29,00
BSV120 order	ANSA 10 uL, PP, peel pack 20 pcs,sterile lotto 24P2003411	10000 exp 31.12.2028	1 000,000	600,00
BSV120 order	ANSA 10 uL, PP, peel pack 20 pcs,sterile lotto 25P2002800	10000 exp 31.01.2029	1 000,000	880,00
BSV1200 order	ANSA 10 uL, PP, peel pack 10 pcs,sterile lotto 25P2002500	12000 exp 31.01.2029	1 000,000	48,00
BSV1201 order	ANSA 10 ul , sterile lotto 25P2002900	2100 exp 31.01.2029	2 100,000	6,00
BSV1205 order	Anse jednorázové, 10ul lotto 25P2002400	4000 exp 31.01.2029	1 000,000	52,00
BSV121 order	ANSA 1 uL, PP, peel pack 20 pcs,sterile lotto 24P2003011	10000 exp 30.11.2028	1 000,000	80,00
BSV121 order	ANSA 1 uL, PP, peel pack 20 pcs,sterile lotto 25P2002200	10000 exp 31.01.2029	1 000,000	1 040,00
BSV1210 order	Anse single-use, volume 1 ul lotto 25P2002700	12000 exp 31.01.2029	1 000,000	36,00
BSV1211 order	ANSA 1 uL, PP,peel pack 1 pcs, sterile lotto 25P2002800	0 exp 31.01.2029	2 100,000	6,00
BSV1215 order	ANSA 1 uL, PP,peel pack 5 pcs, sterile lotto 25P2002300	0 exp 31.01.2029	1 000,000	32,00

202500432  
ACCEPTANCE  
VERIFICATION



### 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.**

**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	29.01.2025	202500432		2 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
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**ACCEPTANCE  
VERIFICATION**

**SHIPPING BY**  
EXW

**ISSUED BY:**  
Božeková

**TRANSPORT**  
SALE

**TRANSPORT START DATE**  
29.01.2025

**DELIVERY TERM**  
EXW

**BOXES**  
348

**PALLETS**  
18

**GROSS WEIGHT KG**  
2 732,49

**NETTO WEIGHT**  
2 513,10

**VOLUME m3**  
19,75

**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*