

# STERIS: Certificate Of Processing

Prepared **STIRILAB**  
For  
Ethylene Oxide Run ID **2002-3690**

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202404105	18

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

## Other Information

Sterilization Batch Number 22A240908

Customer Specification ID: 37

## Signature Manifest

Reviewed and E-Signed By: **Miroslava Hrenakova (Quality Analyst)**

DateTime Esigned 09-Sep-2024 11:04 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 \*\*\*

# Certificate of Analysis



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

**Job No:** **BI-CZE-VEL-202401891**  
**Report Number:** **121101**  
**Date Issued:** **16-Sep-2024**  
**Final Report**  
**Page 1 of 1**

**Purchase Order No:** **202404105**  
**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:** **09-Sep-2024**  
**Date On Test:** **09-Sep-2024**

## Analytical Results

**Label ID / Designation:** **202404105**

**Lot / Sterilization Batch:** **22A240908**

### Microbiology

### Result

#### Biological Indicators

BI Lot Number	488
Number of samples	28
Positive Control Check 7	Positive
Number of positives	0
Negative Controls	Negative
Time on test	09/SEP/24 11:00:00
Time off Test	16/SEP/24 11:54:19

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:

Sarka Mejzlikova

Quality Analyst

Authorisation Date: 16-September-2024

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

Velká Biteš

595 01

# 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:	316120	Pallet Count:	18	Batch No.:	22A240908
Customer:	routine_STIRILAB 03 EQ-15%	Checksum:	1886	Method:	STIRILAB 03 EQ-15%
Specification:	1.3				

## 1.Preconditioning

Equipment:	VB Precond G	Config. Rev.:	Pending
Date Started:	07.09.2024 21:02:27	Date Completed:	08.09.2024 8:19:05
		Duration:	11:16:38

### 1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:16:38	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	46,1 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	51,8 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	51,1 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	60,5 %	45,0 - 95,0 %	✓

### 1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:21:20	n/a - 00:45:00	✓

### Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	07.09.2024 21:02:27	08.09.2024 8:40:25	11:16:38

Process Run Record **Summary**

Run ID 316120

**2.Vessel Processing**

Equipment: **VB Chamber 22** Config. Rev.: **4**  
 Date Started: **08.09.2024 8:40:25** Date Completed: **08.09.2024 19:40:27** Duration: **11:00:02**

**2.1.Start-up Phase**

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Hi	Final - P3	49,6 °C	48,0 - 54,0 °C	✓
TE-CH-Lo	Final - P3	49,6 °C	48,0 - 54,0 °C	✓

**2.2.Vacuum**

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:13:26	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:13:26	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,6 °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	00:00:23	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	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	00:03:46	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:03:46	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 316120

**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	23,1 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	23,9 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	60,1 %	N/A - N/A %	
RH Reported	Max - P22	80,5 %	N/A - N/A %	

**2.7. Vacuum**

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:49	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:49	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	01:03:36	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:03:36	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	50,0 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,1 °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	436,8 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 316120

**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	49,3 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	50,5 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	210,1 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	210,1 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	311,9 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	436,8 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	479,5 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	00:23:11	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:23:11	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,3 °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	00:07:21	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	48,7 °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	00:12:07	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	48,6 °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 316120

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

Phase No. 13

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:07:14	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:14	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,8 °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	✓

**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	49,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,3 °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	00:07:15	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:15	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,1 °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	00:12:07	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	49,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,1 °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	00:07:17	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:17	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,7 °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 316120

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

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:39:15	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:39:15	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	50,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,2 °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	08.09.2024 8:40:25	08.09.2024 19:40:27	11:00:02

Minimum Load Temperature before PRECOND:  $\geq 10,8$  ° C value: 19,6 ° C

SIADTOX 15% - specification: N/A value: 119,8 kg

CYLINDER NR.

1. 9454

2. 1240

3. 7039

4. 1048

**CONFORMING**

Krezek, Ales

Digitally signed by Krezek,  
Alias  
Date: 2024.09.09 10:34:37  
+02'00'

All dates are expressed in the timezone:

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

✓ = Pass

✗ = Fail



# 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:	316121	Pallet Count:	18	Batch No.:	22A240908/DEG
Customer:	DEG_STIRILAB 03-EQ-15%	Checksum:	-23894	Method:	STIRILAB 03 EQ-15%_0h
Specification:	1.16				

## 1.Aeration

Equipment:	VB Aeration 43	Config. Rev.:	Pending
Date Started:	08.09.2024 20:16:14	Date Completed:	09.09.2024 10:31:47
		Duration:	14:15:33

### 1.1.Aeration

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	14:15:33	00:00:00 - 7d 00:00:00	✓
Time-InSpec	Final - P104	14:10:01	00:00:00 - 7d 00:00:00	✓
TE-Min-In-Spec	Min - P101	45,5 °C	41,0 - 51,0 °C	✓
TempAve	Max - P101	47,0 °C	41,0 - 51,0 °C	✓

### Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
1	0	08.09.2024 20:16:14	09.09.2024 10:31:47	14:15:33

# CONFORMING

Krezek,  
Ales

Digitally signed by  
Krezek, Ales  
Date: 2024.09.09  
10:35:12 +02'00'

All dates are expressed in the timezone:

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

✓ = Pass ✗ = Fail



## Transport Document



202404105

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	04.09.2024	202404105		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
BSC740	Fertility collector	40	40,000	63,00
order	lotto 24P2004308 exp 31.07.2028			
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	1 140,00
order	lotto 24P2003406 exp 31.07.2028			
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	60,00
order	lotto 24P2003407 exp 31.08.2028			
BSV1200	ANSA 10 uL, PP, peel pack 10 pcs,sterile	12000	1 000,000	48,00
order	lotto 24P2003303 exp 31.08.2028			
BSV1201	ANSA 10 ul , sterile	2100	2 100,000	8,00
order	lotto 24P2003705 exp 31.08.2028			
BSV1205	Anse jednorázové, 10ul	4000	1 000,000	16,00
order	lotto 24P2003204 exp 31.08.2028			
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	170,00
order	lotto 24P2003007 exp 31.07.2028			
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	1 110,00
order	lotto 24P2003008 exp 31.08.2028			
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	20,00
order	lotto 24P2003009 exp 30.09.2028			
BSV1211	ANSA 1 uL, PP,peel pack 1 pcs, sterile	0	2 100,000	8,00
order	lotto 24P2003604 exp 31.08.2028			
BSV1215	ANSA 1 uL, PP,peel pack 5 pcs, sterile	0	1 000,000	24,00
order	lotto 24P2003103 exp 31.08.2028			



**U.S. FOOD & DRUG  
ADMINISTRATION**

REG. CERTIFICATE NO. 119 810 (21) - 12-1502715.02

**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
	CZ27158621	04.09.2024	202404105		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**

04.09.2024

**DELIVERY TERM**

EXW

**BOXES**

343

**PALLETS**

18

**GROSS WEIGHT KG**

2 566,54

**NETTO WEIGHT**

2 344,47

**VOLUME m3**

19,18

**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*

