

# Certificate of Analysis



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

**Job No:** BI-CZE-VEL-202400960  
**Report Number:** 108823  
**Date Issued:** 24-Jun-2024  
Page 1 of 1

**Purchase Order No:** 202402926  
**Product:** STIRILAB 03 EQ-15%, Biological Indicator  
**Description:** SGM Spore Strip – Bacillus atrophaeus ATCC #9372  
**Standard:** ISO 11138-1:2017  
**Internal Work Instruction:** CZE VEL : LVM-LAB002  
**Customer Method :** STIRILAB 03 EQ-15%

**Date Sample(s) Received:** 17-Jun-2024  
**Date On Test:** 17-Jun-2024

## Analytical Results

**Label ID / Designation:** 202402926

**Lot / Sterilization Batch:** 22240615

**Microbiology**

**Result**

**Biological Indicators**

BI Lot Number	485
Number of samples	28
Positive Control Check 7	Positive
Number of positives	0
Negative Controls	Negative
Time on test	17/JUN/24 10:40:25
Time off Test	24/JUN/24 11:57:48

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.

Method Uncertainties available upon request.

**Released by:**

Ria Collinsova

Laboratory Quality Analyst

**Authorisation Date:** 24-June-2024

## Testing Facility

CZE Velká Bíteš  
STERIS AST CZ s.r.o.  
Prumyslová zóna Košíkov 80

Velká Bíteš

595 01

# STERIS: Certificate Of Processing

Prepared **STIRILAB**  
For  
Ethylene Oxide Run ID **2002-3015**

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202402926	18

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

## Other Information

Sterilization Batch Number 22240615

Customer Specification ID: 37

## Signature Manifest

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

DateTime Esigned 15-Jun-2024 8:16 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: 13058

# 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>313698</b>	Pallet Count:	<b>18</b>	Batch No.:	<b>22240615</b>
Customer:	<b>routine_STIRILAB 03 EQ-15%</b>	Checksum:	<b>1886</b>	Method:	<b>STIRILAB 03 EQ-15%</b>
Specification:	<b>1.3</b>				

## 1.Preconditioning

Equipment:	<b>VB Precond G</b>	Config. Rev.:	<b>Pending</b>		
Date Started:	<b>14.06.2024 8:49:28</b>	Date Completed:	<b>14.06.2024 20:49:40</b>	Duration:	<b>12:00:12</b>

### 1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	12:00:12	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	47,8 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	51,2 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	48,1 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	64,8 %	45,0 - 95,0 %	✓

### 1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:18:53	n/a - 00:45:00	✓

### Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	14.06.2024 8:49:28	14.06.2024 21:08:33	12:00:12

**Process Run Record Summary**

Run ID 313698

**2.Vessel Processing**

Equipment: **VB Chamber 22** Config. Rev.: **4**  
 Date Started: **14.06.2024 21:08:33** Date Completed: **15.06.2024 7:38:56** Duration: **10:30:23**

**2.1.Start-up Phase**

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Hi	Final - P3	48,3 °C	48,0 - 54,0 °C	✓
TE-CH-Lo	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	00:13:21	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:13:21	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	47,8 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	48,3 °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	48,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	48,6 °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	00:00:22	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	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	48,6 °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	00:03:58	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:03:58	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	48,6 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	48,8 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,1 kPa	23,0 - 26,6 kPa	✓

**Process Run Record Summary**

Run ID 313698

**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	48,8 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,4 °C	45,0 - 55,0 °C	✓
PCurr	Min - P14	23,0 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	23,7 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	64,3 %	N/A - N/A %	
RH Reported	Max - P22	84,7 %	N/A - N/A %	

**2.7. Vacuum**

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:43	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:43	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	49,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,4 °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	49,3 °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	429,3 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	476,2 mg/l	N/A - N/A mg/l	

**Process Run Record Summary**

Run ID 313698

**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	49,2 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	50,7 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	209,6 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	209,6 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	304,4 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	429,3 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	476,2 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	478,4 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	00:24:38	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:24:38	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,8 °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	00:07:23	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:23	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,4 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °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	48,2 °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	✓

**Process Run Record Summary**

Run ID 313698

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

Phase No. 13

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	48,5 °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	00:12:07	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	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	00:07:21	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	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	00:12:07	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	48,8 °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	00:07:17	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	48,9 °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	✓

Process Run Record **Summary**

Run ID 313698

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

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:08:26	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:08:26	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	49,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,8 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	93,0 kPa	90,0 - 103,0 kPa	✓
PCurr	Max - P14	93,2 kPa	90,0 - 103,0 kPa	✓

**Stage Summary**

Steps	Deviations	Date Started	Date Ended	Total Duration:
18	0	14.06.2024 21:08:33	15.06.2024 7:38:56	10:30:23

**CONFORMING**

**Trestik,  
Filip** Digitally signed  
by Trestik, Filip  
Date: 2024.06.15  
08:09:37 +02'00'

All dates are expressed in the timezone:

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

✓ = Pass ✗ = Fail





**U.S. FOOD & DRUG  
ADMINISTRATION**  
REGISTRATION NUMBER: 21-18-16279-1-01

**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**

202402926

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	12.06.2024	202402926		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
1131403 order	Anse single-use, packed in envelopes lotto 24P2003800	10000 exp 31.05.2028	1 000,000	200,00
1131404 order	Anse single-use, 10 ul, in envelopes lotto 24P2003900	10000 exp 31.05.2028	1 000,000	800,00
BSC740 order	Fertility collector lotto 24P2004306	40 exp 31.05.2028	40,000	31,00
BSV120 order	ANSA 10 uL, PP, peel pack 20 pcs, sterile lotto 24P2003404	10000 exp 31.05.2028	1 000,000	940,00
BSV120 order	ANSA 10 uL, PP, peel pack 20 pcs, sterile lotto 24P2003405	10000 exp 30.06.2028	1 000,000	70,00
BSV120 order	ANSA 10 uL, PP, peel pack 20 pcs, sterile lotto 24P2003405	10000 exp 30.06.2028	1 000,000	300,00
BSV121 order	ANSA 1 uL, PP, peel pack 20 pcs, sterile lotto 24P2003005	10000 exp 31.05.2028	1 000,000	900,00



**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

**EBSTER 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	12.06.2024	202402926		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

12.06.2024

DELIVERY TERM

EXW

BOXES

352

PALLETS

18

GROSS WEIGHT KG

3 049,03

NETTO WEIGHT

2 802,22

VOLUME m3

20,84

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*

12.6.2024

*[Handwritten Signature]*

ACCEPTANCE VERIFICATION