

# STERIS: Certificate Of Processing

Prepared for STIRILAB

Ethylene Oxide Run ID 2002-2416

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202401934	18

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

## Other Information

Sterilization Batch Number 22A240419

Customer Specification ID: 37

## Signature Manifest

Reviewed and E-Signed By: **Jana Smieskova (Quality Analyst)**

Date/Time E-Signed: 20-Apr-2024 7:54 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: 11234



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

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

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034 01  
Ružomberok

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**Transport Document**

202401934

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	17.04.2024	202401934		1 to 1

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
BSC740	Fertility collector	40	40,000	64,00
order	lotto 24P2004303			exp 31.03.2028
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	1 220,00
order	lotto 24P2003403			exp 30.04.2028
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	1 000,00
order	lotto 24P2003003			exp 31.03.2028
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	580,00
order	lotto 24P2003004			exp 30.04.2028



18. 4. 2024

SHIPPING BY	ISSUED BY:	TRANSPORT	TRANSPORT START DATE
EXW	Božeková	SALE	17.04.2024

  

DELIVERY TERM	BOXES	PALLETS	GROSS WEIGHT KG	NETTO WEIGHT	VOLUME m3	DRIVER'S SIGNATURE
EXW	344	18	2 778,89	2 536,46	20,40	

  

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*

# 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:	312598	Pallet Count:	18	Batch No.:	22A240419
Customer:	routine_STIRILAB 03 EQ-15%	Checksum:	5998	Method:	STIRILAB 03 EQ-15%
Specification:	1.0				

## 1. Preconditioning

Equipment:	VB Precond G	Config. Rev.:	Pending
Date Started:	18.04.2024 19:42:58	Date Completed:	19.04.2024 7:06:41
		Duration:	11:23:43

### 1.1. Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:23:43	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	11:05:00	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	46,1 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	52,1 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	53,8 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	66,1 %	45,0 - 95,0 %	✓

### 1.2. Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:17:19	n/a - 00:45:00	✓

## Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	18.04.2024 19:42:58	19.04.2024 7:24:00	11:23:43

**Process Run Record Summary**

Run ID 312598

**2.Vessel Processing**

Equipment: **VB Chamber 22** Config. Rev.: **4**  
 Date Started: **19.04.2024 7:24:00** Date Completed: **19.04.2024 17:51:51** Duration: **10:27:51**

**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	49,5 °C	48,0 - 54,0 °C	✓

**2.2.Vacuum**

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:13:41	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:13:41	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	49,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,4 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	22,0 kPa	12,0 - 33,0 kPa	✓
PCurr	Max - P14	22,6 kPa	12,0 - 33,0 kPa	✓

**2.4.Vacuum**

Phase No. 4

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:21	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:21	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	49,4 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,4 °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	00:02:23	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:02:23	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	49,4 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,1 kPa	23,0 - 26,6 kPa	✓



Process Run Record **Summary**

Run ID 312598

**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	50,0 °C	45,0 - 55,0 °C	✓
PCurr	Min - P14	22,9 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	23,8 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	62,1 %	N/A - N/A %	
RH Reported	Max - P22	81,8 %	N/A - N/A %	

**2.7. Vacuum**

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:45	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:45	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	01:04:07	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:04:07	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	49,9 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,6 °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	414,1 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	473,1 mg/l	N/A - N/A mg/l	

**Process Run Record Summary**

Run ID 312598

**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	49,4 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,1 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	210,4 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	210,4 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	294,2 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	414,1 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	473,1 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	475,6 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	00:22:55	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:22:55	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,0 °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	00:07:22	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:22	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	93,1 kPa	90,0 - 103,0 kPa	✓

**2.12.Vacuum**

Phase No. 12

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:04	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:04	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	48,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,7 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

**Process Run Record Summary**

Run ID 312598

**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	50,8 °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	49,0 °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	✓

**2.15. Air Inbleed**

Phase No. 15

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	49,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,3 °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	49,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,3 °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	00:07:19	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	49,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,4 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

**Process Run Record Summary**

Run ID 312598

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

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:08:01	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:08:01	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	50,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,4 °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	19.04.2024 7:24:00	19.04.2024 17:51:51	10:27:51

**CONFORMING****Trestik,  
Filip**Digitally signed  
by Trestik, Filip  
Date: 2024.04.20  
07:26:10 +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:	312599	Pallet Count:	18	Batch No.:	22A240419/DEG
Customer:	DEG_STIRILAB 03-EQ-15%	Checksum:	-23894	Method:	STIRILAB 03
Specification:	1.15				EQ-15%_0h

## 1.Aeration

Equipment:	VB Aeration 2	Config. Rev.:	Pending
Date Started:	19.04.2024 20:33:43	Date Completed:	20.04.2024 5:19:12
		Duration:	08:45:29

### 1.1.Aeration

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	08:45:29	00:00:00 - 7d 00:00:00	✓
Time-InSpec	Final - P104	08:40:00	00:00:00 - 7d 00:00:00	✓
TE-Min-In-Spec	Min - P101	45,8 °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	19.04.2024 20:33:43	20.04.2024 5:19:12	08:45:29

# CONFORMING

**Trestik,**  
**Filip** Digitally signed  
by Trestik, Filip  
Date: 2024.04.20  
07:26:53 +02'00'

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

# Certificate of Analysis



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

**Job No:** BI-CZE-VEL-202400142  
**Report Number:** 100791  
**Date Issued:** 29-Apr-2024  
Page 1 of 1

**Purchase Order No:** 202401934  
**Product:** STIRILAB 03 EQ-15%  
**Description:** SGM Spore Strip – Bacillus atrophaeus  
**Standard:** ISO 11138-1:2017  
**Internal Work Instruction:** CZE VEL : LWM-LAB002  
**Customer Method :** STIRILAB 03 EQ-15%

**Date Sample(s) Received:** 22-Apr-2024  
**Date On Test:** 22-Apr-2024

## Analytical Results

**Label ID / Designation:** 202401934

**Lot / Sterilization Batch:** 22A240419

### Microbiology

#### Biological Indicators

### Result

BI Lot Number	485
Number of samples	28
Positive Control Check 7	Positive
Number of positives	0
Negative Controls	Negative
Time off Test	29/APR/24 11:53:33

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:

Sarka Mejzlikova

Quality Analyst

**Authorisation Date:** 29-April-2024

### Testing Facility

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

Velká Bíteš

595 01