

# STERIS: Certificate Of Processing

Prepared for STIRILAB

Ethylene Oxide Run ID 2002-1910

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202401078	18

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

## Other Information

Sterilization Batch Number 22240302

Customer Specification ID: 37

## Signature Manifest

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

Date/Time E-Signed: 02-Mar-2024 8:47 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: 9744

# 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>311728</b>	Pallet Count:	<b>18</b>	Batch No.:	<b>22240302</b>
Customer:	<b>routine_MIX cycle-15%</b>	Checksum:	<b>5998</b>	Method:	<b>MIX cycle-15%</b>
Specification:	<b>1.0</b>				

## 1.Preconditioning

Equipment:	<b>VB Precond G</b>	Config. Rev.:	<b>Pending</b>
Date Started:	<b>01.03.2024 6:27:19</b>	Date Completed:	<b>01.03.2024 18:30:21</b>
		Duration:	<b>12:03:02</b>

### 1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	12:03:02	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	11:50:00	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	46,9 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	52,0 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	51,1 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	60,9 %	45,0 - 95,0 %	✓

### 1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:15:09	n/a - 00:45:00	✓

### Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
<b>2</b>	<b>0</b>	01.03.2024 6:27:19	01.03.2024 18:45:30	12:03:02

**Process Run Record Summary**

Run ID 311728

**2.Vessel Processing**

Equipment: **VB Chamber 22** Config. Rev.: **3**  
 Date Started: **01.03.2024 18:45:30** Date Completed: **02.03.2024 5:35:12** Duration: **10:49:42**

**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	00:14:06	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:14:06	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	47,2 °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	48,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	48,7 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	22,0 kPa	12,0 - 33,0 kPa	✓
PCurr	Max - P14	22,5 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	48,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	48,7 °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	00:04:10	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:04:10	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	48,7 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,0 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,1 kPa	23,0 - 26,6 kPa	✓

**Process Run Record Summary**

Run ID 311728

**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	48,9 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,1 °C	45,0 - 55,0 °C	✓
PCurr	Min - P14	22,9 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	23,7 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	66,7 %	N/A - N/A %	
RH Reported	Max - P22	88,1 %	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	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	01:12:27	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:12:27	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	50,0 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,7 °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	374,8 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	473,9 mg/l	N/A - N/A mg/l	

**Process Run Record Summary**

Run ID 311728

**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	50,6 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	210,7 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	210,7 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	289,1 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	375,2 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	473,9 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	475,3 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	00:23:17	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:23:17	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,2 °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	48,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,9 °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	00:12:03	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:03	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	48,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,9 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

**Process Run Record Summary**

Run ID 311728

**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	48,4 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,8 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,1 kPa	90,0 - 103,0 kPa	✓

**2.14. Vacuum**

Phase No. 14

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:06	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:06	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	48,2 °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	✓

**2.15. 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	48,4 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,6 °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	00:12:05	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:05	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	48,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,6 °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	00:07:16	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	49,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,8 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

**Process Run Record Summary**

Run ID 311728

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

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:19:09	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:19:09	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	50,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,8 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	93,0 kPa	90,0 - 103,0 kPa	✓
PCurr	Max - P14	93,5 kPa	90,0 - 103,0 kPa	✓

**Stage Summary**

Steps	Deviations	Date Started	Date Ended	Total Duration:
18	0	01.03.2024 18:45:30	02.03.2024 5:35:12	10:49:42

**CONFORMING**

**Trestik,**  
**Filip**

Digitally signed  
by Trestik, Filip  
Date: 2024.03.02  
08:35:53 +01'00'

All dates are expressed in the timezone:

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

✓ = Pass ✗ = Fail

Komu: / To **STIRILAB S.R.O.**  
**TEXTILNÁ 23**  
**03401 RUZOMBEROK SLOVENSKÁ REPUBLIKA**

ANALYSIS CERTIFICATE #1594 - BI424 - 03/11/2024

**ČÍSLO CERTIFIKÁTU ANALÝZY 1594 - BI424 - 11/03/2024**Page 1 / 1  
Strana 1 / 1

Our Laboratory Reference Register # BI / 192 - p. 114

**Evidenční číslo: BI / 192 - s. 114**

TITLE: BIOLOGICAL INDICATORS - SPORE STRIP - BACILLUS ATROPHAEUS (B. subtilis var Niger) ATCC #9372

**NÁZEV: BIOLOGICKÝ INDIKÁTOR - SPORE STRIP - BACILLUS ATROPHAEUS (B. Subtilis var Niger) ATCC #9372**

METHOD: ISO 11138-1

METODA: ISO 11138-1

INTERNAL PROCEDURES: LWI-LAB002

VNITŘNÍ PROCEDURA: LWI-LAB002

REFERENCE DATA

**REFERENČNÍ ÚDAJE**

SAMPLES DESCRIPTION: ZDRAVOTNICKÉ PROSTŘEDKY-IN VITRO DIAGNOSTIKA

POPIS VZORKŮ: ZDRAVOTNICKÉ PROSTŘEDKY-IN VITRO DIAGNOSTIKA

REFERENCE: STIRILAB S.R.O.

JMÉNO ZÁKAZNÍKA: STIRILAB S.R.O.

WITHDRAWING MADE BY: STERIS

ODPOVĚDNOST ZA VÝBĚR VZORKŮ: STERIS

RECEIVED BY LABORATORY AT: 03/04/2024

DODÁNO DO LABORATOŘE: 04/03/2024

PRODUCTION BATCH: BILL OF DELIVERY: 202401078

PRODUKČNÍ ŠARŽE: BILL OF DELIVERY: 202401078

STERILIZATION BATCH: 22240302 dtd 03/02/2024

STERILIZAČNÍ ŠARŽE: 22240302 dne 02/03/2024

BI BATCH: BATR 485

BI ŠARŽE: BATR 485

POPULATION (ufc/strip):  $3.7 * 10^6$ POPULACE (cfu / strip):  $3.7 * 10^6$ 

D-value (min): 2.8

D - hodnota (min): 2.8

ANALYSIS PARAMETERS

**PARAMETRY ANALÝZY**

POSITIVE CONTROLS N: 1

POČET POZITIVNÍCH KONTROL: 1

BIOLOGICAL INDICATORS N: 28

POČET BIOLOGICKÝCH INDIKÁTORŮ: 28

GROWTH EVIDENCE AT THE END OF INCUBATION PERIOD

EVIDENCE RŮSTU NA KONCI INKUBAČNÍ DOBY

BI SAMPLES AFTER 7 DAYS

BI PO SEDMI DNECH

POSITIVE CONTROL BI

POZITIVNÍ KONTROLA BI

negative

negativní

positive

pozitivní

Conclusions

**Závěry**

EFFECTIVE STERILIZATION CYCLE

ÚČINNÝ STERILIZAČNÍ CYKLUS

LABORATORY RESPONSIBLE  
ODPOVĚDNÁ OSOBA

11-03-2024

RELEASED BY QUALITY

Šárka Mejzlíková

11. 03. 2024







Transport Document

202401078

**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 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	28.02.2024	202401078		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
7 696 430	Microloops 10 ul sterile	10000	1 000,000	400,00
order	lotto 24P2018600	exp 29.02.2028		
7 696 431	Microloops 1 ul sterile	10000	1 000,000	200,00
order	lotto 24P2018500	exp 29.02.2028		
7 696 431	Microloops 1 ul sterile	10000	1 000,000	100,00
order	lotto 24P2018500	exp 29.02.2028		
BSC740	Fertility collector	40	40,000	64,00
order	lotto 24P2004302	exp 29.02.2028		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	760,00
order	lotto 24P2003401	exp 31.01.2028		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	100,00
order	lotto 24P2003402	exp 29.02.2028		
BSV1200	ANSA 10 uL, PP, peel pack 10 pcs,sterile	12000	1 000,000	180,00
order	lotto 24P2003301	exp 29.02.2028		
BSV1201	ANSA 10 ul , sterile	2100	2 100,000	16,00
order	lotto 24P2003702	exp 29.02.2028		
BSV1205	Anse jednorázové, 10ul	4000	1 000,000	20,00
order	lotto 24P2003201	exp 29.02.2028		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	300,00
order	lotto 24P2003001	exp 29.02.2028		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	400,00
order	lotto 24P2003002	exp 29.02.2028		
BSV1211	ANSA 1 uL, PP,peel pack 1 pcs, sterile	0	2 100,000	14,00
order	lotto 24P2003601	exp 29.02.2028		
BSV1215	ANSA 1 uL, PP,peel pack 5 pcs, sterile	0	1 000,000	16,00
order	lotto 24P2003100	exp 29.02.2028		



### 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 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	28.02.2024	202401078		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

28.02.2024

DELIVERY TERM

EXW

BOXES

344

PALLETS

18

GROSS WEIGHT KG

2 417,61

NETTO WEIGHT

2 219,06

VOLUME m3

17,83

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.*