

Certificate of Analysis



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

Job No:
Report Number:
Date Issued:
Final Report
BI-CZE-VEL-202502981
174454
04-Aug-2025
Page 1 of 1

Purchase Order No: 202503342
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 : LWI-LAB002
Customer Protocol: STIRILAB 03 EQ-15%

Date Sample(s) Received: 25-Jul-2025
Date On Test: 25-Jul-2025

Analytical Results

Label ID / Designation: 202503342

Lot / Sterilization Batch: 22250725

Microbiology

Result

Biological Indicators

BI Lot Number	494
Number of samples	28
Positive Control Check 7	Positive
Number of positives	0
Negative Controls	Negative
Time on test	25/JUL/2025 10:20
Time off Test	04/AUG/2025 07:37

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:

04-August-2025

Laboratory Operation Manager

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

Velká Bíteš

595 01

STERIS: Certificate Of Processing

Prepared STIRILAB SRO
For
Ethylene Oxide Run ID 2002-7859

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202503342	18

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

Other Information

Sterilization Batch Number 22250725

Customer Specification ID: 55

Signature Manifest

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

DateTime Esigned 25-Jul-2025 7:59 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: 26915

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:	321195	Pallet Count:	18	Batch No.:	22250725
Customer:	routine_STIRILAB 03 EQ-15%	Checksum:	-1107	Method:	STIRILAB 03 EQ-15%
Specification:	1.6				

1.Preconditioning

Equipment:	VB Precond G	Config. Rev.:	Pending
Date Started:	24.07.2025 6:39:25	Date Completed:	24.07.2025 18:11:03
		Duration:	11:31:38

1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:31:38	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	11:15:00	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	48,6 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	51,7 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	50,9 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	62,4 %	45,0 - 95,0 %	✓

1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:10:05	n/a - 00:45:00	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	24.07.2025 6:39:25	24.07.2025 18:21:08	11:31:38

Process Run Record Summary

Run ID 321195

2.Vessel Processing

Equipment: VB Chamber 22

Config. Rev.: 6

Date Started: 24.07.2025 18:21:08

Date Completed: 25.07.2025 5:14:50

Duration: 10:53:42

2.1.Start-up Phase

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Lo	Final - P3	48,8 °C	48,0 - 54,0 °C	✓
TE-CH-Hi	Final - P3	48,9 °C	48,0 - 54,0 °C	✓

2.2.Vacuum

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:13:18	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:13:18	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,8 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,8 °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	49,8 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,3 °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	50,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,3 °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	00:04:22	00:01:00 - 00:20:00	✓
Total Phase Time	Final - P11	00:04:22	00:01:00 - 00:20:00	✓
TE-CH-Lo	Min - P3	50,3 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,5 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,2 kPa	23,0 - 26,6 kPa	✓

Process Run Record Summary

Run ID 321195

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 - 01:32:00	✓
Total Phase Time	Final - P11	01:25:01	01:10:00 - 01:32:00	✓
TE-CH-Lo	Min - P3	50,4 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,7 °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	72,4 %	N/A - N/A %	
RH Reported	Max - P22	92,2 %	N/A - N/A %	

2.7. Vacuum

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:39	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:39	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	50,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,4 °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	01:04:05	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:04:05	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	50,3 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,2 °C	46,0 - 54,0 °C	✓
PCurr	Final - P14	215,0 kPa	200,0 - 225,0 kPa	✓
PCurr	Final - P1028	215,0 kPa	n/a - N/A kPa	
EO Conc. Reported	Final - P33	436,9 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	478,6 mg/l	N/A - N/A mg/l	

Process Run Record Summary

Run ID 321195

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	50,8 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	209,3 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	209,3 kPa	N/A - N/A kPa	
PCurr	Max - P14	215,0 kPa	200,0 - 225,0 kPa	✓
PCurr	Max - P1028	215,0 kPa	N/A - N/A 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	436,9 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	478,6 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	480,3 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	00:21:34	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:21:34	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,1 °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	00:07:31	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:31	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,4 °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	00:12:08	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:08	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

Process Run Record Summary

Run ID 321195

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

Phase No. 13

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	48,8 °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	48,9 °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	00:07:25	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:25	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,0 °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	00:12:08	00:12:00 - 00:28:00	✓
Total Phase Time	Final - P11	00:12:08	00:12:00 - 00:28:00	✓
TE-CH-Lo	Min - P3	49,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,0 °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	00:07:24	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:24	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,5 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,0 kPa	90,0 - 103,0 kPa	✓

Process Run Record Summary

Run ID 321195

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

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:33:06	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:33:06	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	50,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,5 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	93,0 kPa	90,0 - 103,0 kPa	✓
PCurr	Max - P14	93,8 kPa	90,0 - 103,0 kPa	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
18	0	24.07.2025 18:21:08	25.07.2025 5:14:50	10:53:42

3.Aeration

Equipment:	VB Aeration 07	Config. Rev.:	Pending
Date Started:	25.07.2025 6:43:10	Date Completed:	25.07.2025 7:35:15
		Duration:	00:52:05

3.1.Aeration

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	00:52:05	00:00:00 - 7d 00:00:00	✓
Time-InSpec	Final - P104	00:50:00	00:00:00 - 7d 00:00:00	✓
TE-Min-In-Spec	Min - P101	45,8 °C	41,0 - 51,0 °C	✓
TempAve	Max - P101	46,6 °C	41,0 - 51,0 °C	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
1	0	25.07.2025 6:43:10	25.07.2025 7:35:15	00:52:05

Minimum Load Temperature before PRECOND: ≥ 10,8 ° C value: 18,2 ° C
SIADTOX 15% - specification: N/A value: 120,3 kg
CYLINDER NR.
1. 11622
2. 7333
3. 3177
4. 58966

CONFORMING

Vrbka,
Vojtech

Digitálně podepsal
Vrbka, Vojtech
Datum: 2025.07.25
07:36:53 +02'00'



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



202503342

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

595 01 Velká Bíteš Česká republika

CUST. NO.	VAT CODE	DATE	TD NUMBER	ISSUED BY	PAGE
	CZ27159621	22.07.2025	202503342		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
BSC740	Fertility collector	40	40,000	78,00
order	lotto 25P2005605	exp 31.07.2029		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	40,00
order	lotto 25P2002604	exp 30.04.2029		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	1 480,00
order	lotto 25P2002608	exp 31.07.2029		
BSV1201	ANSA 10 uL, sterile	2100	2 100,000	4,00
order	lotto 25P2002905	exp 31.07.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	280,00
order	lotto 25P2002205	exp 30.06.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	740,00
order	lotto 25P2002206	exp 31.07.2029		
BSV1211	ANSA 1 uL, PP, peel pack 1 pcs, sterile	0	2 100,000	6,00
order	lotto 25P2002803	exp 31.07.2029		
BSV1215	ANSA 1 uL, PP, peel pack 5 pcs, sterile	0	1 000,000	9,00
order	lotto 25P2002303	exp 31.07.2029		

ACCEPTANCE
VERIFICATION

22.7.25
13 30



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

**Textilná 23
034 01**

Ružomberok

VAT No. SK2021729545

Telex +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

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

595 01 Velká Bíteš Česká republika

CUST. NO.	VAT CODE	DATE	TD NUMBER	ISSUED BY	PAGE
	CZ27158621	22.07.2025	202503342		2 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
------	-------------	-------------	----	----------

SHIPPING BY

EXW

ISSUED BY:

Božeková

TRANSPORT

SALE

TRANSPORT START DATE

22.07.2025

DELIVERY TERM

EXW

BOXES

344

PALLETS

18

GROSS WEIGHT KG

2 663,34

NETTO WEIGHT

2 434,14

VOLUME m3

19,89

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