

Certificate of Analysis



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

SVK
03401

Purchase Order No: 202501366
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 : LWM-LAB002
Customer Protocol: STIRILAB 03 EQ-15%

Job No: BI-CZE-VEL-202501190
Report Number: 154360
Date Issued: 07-Apr-2025
Page 1 of 1

Date Sample(s) Received: 31-Mar-2025
Date On Test: 31-Mar-2025

Analytical Results

Label ID / Designation: 202501366

Lot / Sterilization Batch: 22A250328

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	31-03-2025 10:15:00
Time off Test	07-04-2025 10:53:54

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:

07-April-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 2002-6066

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202501366	18

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

Other Information

Sterilization Batch Number 22A250328

Customer Specification ID: 55

Signature Manifest

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

DateTime Esigned 29-Mar-2025 6:47 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: 21775

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:	319285	Pallet Count:	18	Batch No.:	22A250328
Customer:	routine_STIRILAB 03 EQ-15%	Checksum:	-14460	Method:	STIRILAB 03 EQ-15%
Specification:	1.4				

1.Preconditioning

Equipment:	VB Precond G	Config. Rev.:	Pending
Date Started:	27.03.2025 18:37:02	Date Completed:	28.03.2025 6:08:20
		Duration:	11:31:18

1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:31:18	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	11:10:01	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	47,0 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	52,3 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	53,7 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	61,3 %	45,0 - 95,0 %	✓

1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:16:40	n/a - 00:45:00	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	27.03.2025 18:37:02	28.03.2025 6:25:00	11:31:18

Process Run Record Summary

Run ID 319285

2.Vessel Processing

Equipment: VB Chamber 22

Config. Rev.: 6

Date Started: 28.03.2025 6:25:00

Date Completed: 28.03.2025 17:04:53

Duration: 10:39:53

2.1.Start-up Phase

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Hi	Final - P3	49,2 °C	48,0 - 54,0 °C	✓
TE-CH-Lo	Final - P3	49,2 °C	48,0 - 54,0 °C	✓

2.2.Vacuum

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:13:05	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:13:05	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,8 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	21,9 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	49,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,1 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	21,9 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	00:00:21	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	50,1 °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	✓

2.5.Steam Inject by Pressure

Phase No. 5

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:03:36	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:03:36	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	50,1 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,4 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,1 kPa	23,0 - 26,6 kPa	✓

Process Run Record Summary

Run ID 319285

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	50,3 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,0 °C	45,0 - 55,0 °C	✓
PCurr	Min - P14	23,1 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	23,5 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	74,5 %	N/A - N/A %	
RH Reported	Max - P22	93,8 %	N/A - N/A %	

2.7. Vacuum

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:36	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:36	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	50,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,5 °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	01:03:56	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:03:56	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	50,5 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,4 °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	406,4 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	474,6 mg/l	N/A - N/A mg/l	

Process Run Record Summary

Run ID 319285

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	49,8 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	50,8 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	210,0 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	210,0 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	406,7 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	474,6 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	476,0 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	00:21:51	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:21:51	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,1 °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	00:07:23	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	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,6 °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	48,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,6 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	27,0 kPa	17,0 - 37,0 kPa	✓

Process Run Record Summary

Run ID 319285

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

Phase No. 13

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	50,4 °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	00:12:08	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	50,4 °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	00:07:18	00:03:00 - 00:17:00	✓
Total Phase Time	Final - P11	00:07:18	00:03:00 - 00:17:00	✓
TE-CH-Lo	Min - P3	49,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,2 °C	40,0 - 55,0 °C	✓
PCurr	Final - P14	93,1 kPa	90,0 - 103,0 kPa	✓

2.16. Vacuum

Phase No. 16

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:12:09	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	49,8 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,2 °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	50,0 °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	✓

Process Run Record Summary

Run ID 319285

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

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:20:39	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:20:39	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	51,1 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	51,6 °C	40,0 - 55,0 °C	✓
PCurr	Min - P14	93,0 kPa	90,0 - 103,0 kPa	✓
PCurr	Max - P14	93,7 kPa	90,0 - 103,0 kPa	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
18	0	28.03.2025 6:25:00	28.03.2025 17:04:53	10:39:53

3.Aeration

Equipment:	VB Aeration 03	Config. Rev.:	Pending
Date Started:	28.03.2025 17:41:53	Date Completed:	29.03.2025 5:10:29
		Duration:	11:28:36

3.1.Aeration

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:28:36	00:00:00 - 7d 00:00:00	✓
Time-InSpec	Final - P104	11:25:00	00:00:00 - 7d 00:00:00	✓
TE-Min-In-Spec	Min - P101	45,7 °C	41,0 - 51,0 °C	✓
TempAve	Max - P101	47,2 °C	41,0 - 51,0 °C	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
1	0	28.03.2025 17:41:53	29.03.2025 5:10:29	11:28:36

Minimum Load Temperature before PRECOND: ≥ 10,8 ° C value: 18,2 ° C
SIADTOX 15% - specification: N/A value: 120,3 kg
CYLINDER NR.
1. 3242
2. 11914
3. 1247
4. 3508

CONFORMING

Malina, Milan

Digitally signed by Malina, Milan
Date: 2025.03.29 06:37:22
+01'00'



U.S. FOOD & DRUG
ADMINISTRATION
REGISTRATION NUMBER: 371037120

Transport Document

202501366

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

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

CUST. NO.	VAT CODE	DATE	TD NUMBER	ISSUED BY	PAGE
	CZ27159621	25.03.2025	202501366		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
BSC740	Fertility collector	40	40,000	2,00
order	lotto 24P2004311	exp 31.10.2028		
BSC740	Fertility collector	40	40,000	4,00
order	lotto 24P2004313	exp 31.12.2028		
BSC740	Fertility collector	40	40,000	16,00
order	lotto 25P2005601	exp 28.02.2029		
BSC740	Fertility collector	40	40,000	42,00
order	lotto 25P2005602	exp 31.03.2029		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	1 340,00
order	lotto 25P2002602	exp 31.03.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	670,00
order	lotto 25P2002201	exp 28.02.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	130,00
order	lotto 25P2002202	exp 31.03.2029		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	600,00
order	lotto 25P2002203	exp 31.03.2029		
BSV1210	Anse single-use, volume 1 ul	12000	1 000,000	72,00
order	lotto 25P2002701	exp 31.03.2029		

ACCEPTANCE
VERIFICATION

24.2.2025
900



U.S. FOOD & DRUG
ADMINISTRATION
REGISTRATION NUMBER: N15270136

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

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	25.03.2025	202501386		2 to 2

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

SHIPPING BY

EXW

ISSUED BY:

Božeková

TRANSPORT

SALE

TRANSPORT START DATE

25.03.2025

DELIVERY TERM

EXW

BOXES

344

PALLETS

18

GROSS WEIGHT KG

2 821,63

NETTO WEIGHT

2 580,57

VOLUME m3

20,43

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

ACCEPTANCE
VERIFICATION

24.3.2025
9:00