

STERIS: Certificate Of Processing

Prepared STIRILAB
For
Ethylene Oxide Run ID 2002-3157

Product Code	Lot Number	Quantity (PL)
STIRILAB 03 EQ-15%	202403181	18

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

Other Information

Sterilization Batch Number 22A240628

Customer Specification ID: 37

Signature Manifest

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

DateTime Signed 29-Jun-2024 8:44 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 ***

Certificate of Analysis



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

Job No: BI-CZE-VEL-202401168
Report Number: 110887
Date Issued: 08-Jul-2024
Page 1 of 1

Purchase Order No: 202403181
Product: STIRILAB 03 EQ-15%, Biological Indicator
Description: SGM Spore Strip – Bacillus atrophaeus ATCC #9372
Standard Method: ISO 11138-1:2017 - only Paragraph 7
Internal Work Instruction: CZE VEL : LWM-LAB002
Customer Protocol: STIRILAB 03 EQ-15%

Date Sample(s) Received: 01-Jul-2024
Date On Test: 01-Jul-2024

Analytical Results

Label ID / Designation: 202403181

Lot / Sterilization Batch: 22A240628

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	01/JUL/24 10:00:00
Time off Test	08/JUL/24 10:21:42

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:

Ria Collinsova

Laboratory Quality Analyst

Authorisation Date: 08-July-2024

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

Velká Bíteš

595 01

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:	313975	Pallet Count:	18	Batch No.:	22A240628
Customer:	routine_STIRILAB 03 EQ-15%	Checksum:	1886	Method:	STIRILAB 03 EQ-15%
Specification:	1.3				

1.Preconditioning

Equipment:	VB Precond G	Config. Rev.:	Pending
Date Started:	27.06.2024 18:16:52	Date Completed:	28.06.2024 5:42:53
		Duration:	11:26:01

1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	11:26:01	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	45,4 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	51,6 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	45,7 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	64,6 %	45,0 - 95,0 %	✓

1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:21:54	n/a - 00:45:00	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	27.06.2024 18:16:52	28.06.2024 6:04:47	11:26:01

Process Run Record Summary

Run ID 313975

2.Vessel Processing

Equipment: VB Chamber 22

Config. Rev.: 4

Date Started: 28.06.2024 6:04:47

Date Completed: 28.06.2024 16:31:20

Duration: 10:26:33

2.1.Start-up Phase

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Hi	Final - P3	48,8 °C	48,0 - 54,0 °C	✓
TE-CH-Lo	Final - P3	48,7 °C	48,0 - 54,0 °C	✓

2.2.Vacuum

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:13:28	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:13:28	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	48,8 °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	48,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	48,9 °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	48,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	48,9 °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	00:03:44	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:03:44	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	48,9 °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 313975

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	50,2 °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	61,8 %	N/A - N/A %	
RH Reported	Max - P22	83,7 %	N/A - N/A %	

2.7. Vacuum

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:45	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	50,2 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,2 °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	01:03:55	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:03:55	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	50,2 °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	421,6 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Final - P33	476,9 mg/l	N/A - N/A mg/l	

Process Run Record Summary

Run ID 313975

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	51,0 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	209,5 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	209,5 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	304,3 mg/l	N/A - N/A mg/l	
EO Conc. Reported	Max - P33	421,6 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Min - P33	476,9 mg/l	N/A - N/A mg/l	
EO Conc. Calculated	Max - P33	479,2 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	00:23:22	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:23:22	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	47,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,3 °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	00:07:24	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	48,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °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	00:12:07	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	48,4 °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 313975

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	48,7 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,3 °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	50,3 °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	51,0 °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	49,5 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	50,9 °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	00:07:18	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	49,7 °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	✓

Stage » Vessel Processing

2.18.End Phase

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:05:11	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:05:11	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	50,7 °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	93,1 kPa	90,0 - 103,0 kPa	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
18	0	28.06.2024 6:04:47	28.06.2024 16:31:20	10:26:33

CONFORMING

Krezek,
Ales

Digitally signed by
Krezek, Ales
Date: 2024.06.29
08:21:24 +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:	313976	Pallet Count:	18	Batch No.:	22A240628/DEG
Customer:	DEG_STIRILAB 03-EQ-15%	Checksum:	-23894	Method:	STIRILAB 03
Specification:	1.16				EQ-15%_0h

1.Aeration

Equipment:	VB Aeration 36	Config. Rev.:	Pending
Date Started:	28.06.2024 19:54:20	Date Completed:	29.06.2024 5:36:30
		Duration:	09:42:10

1.1.Aeration

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	09:42:10	00:00:00 - 7d 00:00:00	✓
Time-InSpec	Final - P104	09:40:01	00:00:00 - 7d 00:00:00	✓
TE-Min-In-Spec	Min - P101	45,6 °C	41,0 - 51,0 °C	✓
TempAve	Max - P101	47,6 °C	41,0 - 51,0 °C	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
1	0	28.06.2024 19:54:20	29.06.2024 5:36:30	09:42:10

CONFORMING

Krezek,
Ales

Digitally signed by
Krezek, Ales
Date: 2024.06.29
08:20:33 +02'00'

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



U.S. FOOD & DRUG
ADMINISTRATION

Transport Document



202403181

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 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	28.06.2024	202403181		1 to 1

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
BSC740	Fertility collector	40	40,000	17,00
order	lotto 24P2004306	exp 31.05.2028		
BSC740	Fertility collector	40	40,000	43,00
order	lotto 24P2004307	exp 30.06.2028		
BSV120	ANSA 10 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	1 750,00
order	lotto 24P2003405	exp 30.06.2028		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	250,00
order	lotto 24P2003005	exp 31.05.2028		
BSV121	ANSA 1 uL, PP, peel pack 20 pcs,sterile	10000	1 000,000	880,00
order	lotto 24P2003006	exp 30.06.2028		



77:30
27.6.24

SHIPPING BY

EXW

ISSUED BY:

Božeková

TRANSPORT

SALE

TRANSPORT START DATE

26.06.2024

DELIVERY TERM

EXW

BOXES

348

PALLETS

16

GROSS WEIGHT KG

2 914,30

NETTO WEIGHT

2 677,34

VOLUME m3

20,71

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