

STERIS: Certificate Of Processing

Prepared STIRILAB
For
Ethylene Oxide Run ID 2002-4575

<u>Product Code</u>	<u>Lot Number</u>	<u>Quantity (PL)</u>
STIRILAB 03 EQ-15%	202405346	18

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

Other Information

Sterilization Batch Number 22A241122

Customer Specification ID: 37

Signature Manifest

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

DateTime Signed 23-Nov-2024 7:00 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: 17568

Certificate of Analysis



Customer:Stirilab s.r.o.

Address:Textilná 23
Ružomberok

Purchase Order No:202405346

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 : LM-LAB002

Customer Protocol:STIRILAB 03 EQ-15%

SVK
03401

Job No:
Report Number:
Date Issued:

Final Report
BI-CZE-VEL-202403040
134081
02-Dec-2024
Page 1 of 1

Date Sample(s) Received:25-Nov-2024

Date On Test:25-Nov-2024

Analytical Results

Label ID / Designation:202405346

Lot / Sterilization Batch:22A241122

Microbiology

Biological Indicators

Result

BI Lot Number

Number of samples

Positive Control Check 7

Number of positives

Negative Controls

Time on test

Time off Test

488

28

Positive

0

Negative

25/NOV/24 10:45:30

02/DEC/24 12:08:29

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:02-December-2024

Laboratory Operation Manager

Testing Facility

CZE Velka Bites

STERIS AST CZ s.r.o.

Prumyslová zóna Košíkov 80

Velká Bíteš

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:	317494	Pallet Count:	18	Batch No.:	22A241122
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:	21.11.2024 18:30:05	Date Completed:	22.11.2024 7:52:37
		Duration:	13:22:32

1.1.Preconditioning

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
Total Phase Time	Final - P104	13:22:32	11:00:00 - 1d 00:00:00	✓
Time-InSpec	Final - P104	13:10:00	11:00:00 - 1d 00:00:00	✓
TE-Min-In-Spec	Min - P101	48,3 °C	45,0 - 55,0 °C	✓
TempAve	Max - P101	51,3 °C	45,0 - 55,0 °C	✓
RH-Min-In-Spec	Min - P22	50,2 %	45,0 - 95,0 %	✓
AT-RH-Avg	Max - P22	64,7 %	45,0 - 95,0 %	✓

1.2.Transfer to Vessel

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
Transfer Duration	Final - P104	00:14:55	n/a - 00:45:00	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
2	0	21.11.2024 18:30:05	22.11.2024 8:07:32	13:22:32

Process Run Record Summary

Run ID 317494

2.Vessel Processing

Equipment: VB Chamber 22 Config. Rev.: 4
Date Started: 22.11.2024 8:07:32 Date Completed: 22.11.2024 18:33:52 Duration: 10:26:20

2.1.Start-up Phase

Phase No. 1

Device	Summary	Summary Value	Specified Range	✓/✗
TE-CH-Hi	Final - P3	48,4 °C	48,0 - 54,0 °C	✓
TE-CH-Lo	Final - P3	48,4 °C	48,0 - 54,0 °C	✓

2.2.Vacuum

Phase No. 2

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:14:04	00:10:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:14:04	00:10:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	48,6 °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	48,6 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,0 °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	00:00:23	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:23	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	48,9 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,0 °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	00:04:00	00:01:00 - 00:12:00	✓
Total Phase Time	Final - P11	00:04:00	00:01:00 - 00:12:00	✓
TE-CH-Lo	Min - P3	48,9 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,1 °C	45,0 - 55,0 °C	✓
PCurr	Final - P14	23,1 kPa	23,0 - 26,6 kPa	✓

Process Run Record Summary

Run ID 317494

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	49,1 °C	45,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °C	45,0 - 55,0 °C	✓
PCurr	Min - P14	23,0 kPa	22,0 - 26,6 kPa	✓
PCurr	Max - P14	23,5 kPa	22,0 - 26,6 kPa	✓
RH Reported	Min - P22	64,3 %	N/A - N/A %	
RH Reported	Max - P22	85,2 %	N/A - N/A %	

2.7. Vacuum

Phase No. 7

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:00:40	00:00:01 - 00:05:00	✓
Total Phase Time	Final - P11	00:00:40	00:00:01 - 00:05:00	✓
TE-CH-Lo	Min - P3	49,4 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °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	01:05:02	00:45:00 - 01:30:00	✓
Total Phase Time	Final - P11	01:05:02	00:45:00 - 01:30:00	✓
TE-CH-Lo	Min - P3	49,4 °C	46,0 - 54,0 °C	✓
TE-CH-Hi	Max - P3	51,5 °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	473,0 mg/l	N/A - N/A mg/l	

Process Run Record Summary

Run ID 317494

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	51,2 °C	46,0 - 54,0 °C	✓
PCurr	Min - P14	209,4 kPa	200,0 - 225,0 kPa	✓
PCurr	Min - P1028	209,4 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	304,5 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	473,0 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	00:23:41	00:15:00 - 00:45:00	✓
Total Phase Time	Final - P11	00:23:41	00:15:00 - 00:45:00	✓
TE-CH-Lo	Min - P3	48,0 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,8 °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	48,3 °C	40,0 - 55,0 °C	✓
TE-CH-Hi	Max - P3	49,5 °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	00:12:07	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 317494

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	48,6 °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	48,9 °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	00:07:15	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	49,0 °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	00:12:07	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	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	00:07:19	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	49,2 °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	✓

Stage » Vessel Processing

2.18.End Phase

Phase No. 18

Device	Summary	Summary Value	Specified Range	✓/✗
In-Spec Phase Time	Final - P11	00:02:52	00:00:01 - 05:00:00	✓
Total Phase Time	Final - P11	00:02:52	00:00:01 - 05:00:00	✓
TE-CH-Lo	Min - P3	50,5 °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	93,1 kPa	90,0 - 103,0 kPa	✓

Stage Summary

Steps	Deviations	Date Started	Date Ended	Total Duration:
18	0	22.11.2024 8:07:32	22.11.2024 18:33:52	10:26:20

Minimum Load Temperature before PRECOND: ≥ 10,8 ° C value: 19,5 ° C
SIADTOX 15% - specification: N/A value: 119,9 kg
CYLINDER NR.
1. 2086
2. 2055
3. 9489
4. 3516

CONFORMING

Malina, Milan

Digitally signed by Malina, Milan
Date: 2024.11.23 06:52:16
+01'00'



**U.S. FOOD & DRUG
ADMINISTRATION**
REGISTRATION NUMBER: 2810270339

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



202405346

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	20.11.2024	202405346		1 to 2

CODE	DESCRIPTION	QTY per BOX	MU	QUANTITY
1131403	Anse single-use, packed in envelopes	10000	1 000,000	200,00
order	lotto 24P2003801 exp 31.10.2028			
1131404	Anse single-use, 10 ul. in envelopes	10000	1 000,000	800,00
order	lotto 24P2003901 exp 30.11.2028			
BSC740	Fertility collector	40	40,000	18,00
order	lotto 24P2004310 exp 31.10.2028			
BSC740	Fertility collector	40	40,000	46,00
order	lotto 24P2004311 exp 31.10.2028			
BSV120	ANSA 10 uL, PP, peel pack 20 pcs, sterile	10000	1 000,000	130,00
order	lotto 24P2003409 exp 31.10.2028			
BSV120	ANSA 10 uL, PP, peel pack 20 pcs, sterile	10000	1 000,000	1 010,00
order	lotto 24P2003410 exp 30.11.2028			
BSV121	ANSA 1 uL, PP, peel pack 20 pcs, sterile	10000	1 000,000	520,00
order	lotto 24P2003010 exp 31.10.2028			
BSV121	ANSA 1 uL, PP, peel pack 20 pcs, sterile	10000	1 000,000	80,00
order	lotto 24P2003011 exp 30.11.2028			
BSV1211	ANSA 1 uL, PP, peel pack 1 pcs, sterile	0	2 100,000	6,00
order	lotto 24P2003606 exp 30.11.2028			



U.S. FOOD & DRUG
ADMINISTRATION

REGISTRATION NUMBER: 301227232

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
	CZ27159621	20.11.2024	202405346		2 to 2

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

SHIPPING BY

EXW

ISSUED BY:

Božeková

TRANSPORT

SALE

TRANSPORT START DATE

20.11.2024

DELIVERY TERM

EXW

BOXES

344

PALLETS

18

GROSS WEIGHT KG

2 739,81

NETTO WEIGHT

2 500,66

VOLUME m3

20,04

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

ACCEPTANCE
VERIFICATION

21.11.2024