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VOL-01

PERFORMANCE QUALIFICATION PROTOCOL

Annex-01.01

Results Data Sheets

FOR

AUTOCLAVE

(M-AUX-AU014)

OF

MIDDLE EAST FOR VACCINES (MEVAC)

AL-SALEHIA

CLIENT: MEVAC

QUALIFICATION PROVIDER: TAG TECHNO AIR GATE

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Table of Content

1. REPORT REVIEW AND APPROVAL

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Name	Title	Company	Date	Signature
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Name	Title	Company	Date	Signature
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TAG Approver(s)

Name	Title	Company	Date	Signature
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MIDDLE EAST FOR VACCINES (MEVAC) Reviewer(s)

Name	Title	Company	Date	Signature

MIDDLE EAST FOR VACCINES (MEVAC) Approver(s)

Name	Title	Company	Date	Signature

Change History				
No.	Revision No.	Amended Page No.	Reason for change	Issued Date
1.	00	NA	Original	30-06-2025

Note: Any amendment will be indicated with italic and bold font.

CALIBRATION TAG TECHNO AIR GATE

2. INTRODUCION

2.1. Report Purpose

The purpose of this report is to document the results of the performance qualification study conducted to evaluate the heat distribution within the Autoclave located at MIDDLE EAST FOR VACCINES (MEVAC). The report includes the following points:

2.1.1 Detailed tables for the main cycle(s) conducted presenting the recorded:

- Average, maximum, and minimum recorded temperature for each location.
- F_0-value for each location.
- Average temperature across all locations.

2.1.2 Identifying the hottest and coolest points and illustrating their locations on the layout diagram.

2.1.3 Identifying any excursions or abnormal variations observed during the study and providing a summary of those deviations in the deviation report along with any corrective action taken.

2.2. System Brief Description

The scope of this report intends to cover the performance qualification results of Autoclave (M-AUX-AU014) located at MIDDLE EAST FOR VACCINES (MEVAC) with the following description:

System Brief Description	
Description	Autoclave
Dimensions/Volume	53 Liter
Manufacturing	TOMY
Model	SX-500
S.N.	53133024
Code	M-AUX-AU014
Location	Washing B.1.2.240

2.3. Associated Material and Equipment Description

Used Reference Equipment Description						
Description	No. of sensors	Range	Accuracy	Manufacturer	Model	Calibration Due Date
Data Loggers	10 sensors	(-40) °C to (140) °C	± 0.5 °C	Tecnosoft s.r.l.	SterilDisk Probe	Nov., 2025
Data Loggers	01 sensors	(0) bar to (4) bar	± 5% of F.S	Tecnosoft s.r.l.	PressureDisk 05	Nov., 2025

2.4. Study Design

Heat Distribution Study Design	
Sterilization Temp. Setting	122 °C
Accepted Sterilization Temp.	(121 - 125) °C
Sterilization Time Setting	for 20 min
Accepted Sterilization Time	NLT 20 min
Accepted F_0-value	≥ 15 (as per customer requirement)

Cycle No.	Cycle Description	Load Description	Start Date	Stop Date	Sample Frequency
1.	Max. Solid distribution	2 Bottles (200 ml) & silicon tools	26/06/2025 12:26:00 PM	26/06/2025 02:08:15 PM	15 seconds
2.	Max. Solid penetration	2 Bottles (200 ml) & silicon tools with BI	26/06/2025 02:25:00 PM	26/06/2025 04:08:15 PM	15 seconds

3. RESULTS DATA SHEETS

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RESULTs DATA SHEETs

DATA SHEET 01.01.01

MAIN CYCLES TEST RESULTS

Content:

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RESULTs DATA SHEETs

DATA SHEET 01.01.01.01

SOLID DISTRIBUTION CYCLE TEST RESULTS

CALIBRATION TAG TECHNO AIR GATE

Datasheet number 01.01.01.01.01: Maximum Solid distribution Cycle Test Results Data Sheets

Heat Distribution Study Data Sheet for Autoclave (M-AUX-AU014)			
Cycle No.	1 of 2		
Cycle Name	Maximum Solid distribution Cycle		
Load Description	2 Bottles (200 ml) & silicon tools		
Sterilization Temp. Setting	122 °C		
Accepted Sterilization Temp.	(121 - 125) °C		
Sterilization Time Setting	for 20 min		
Accepted Sterilization Time	NLT 20 min		
Accepted F_0-value	≥ 15 (as per customer requirement)		
Cycle Start Time	26/06/2025 12:26:00 PM	Cycle End Time	26/06/2025 02:08:00 PM
Sterilization Start Time	26/06/2025 01:14:00 PM	Sterilization End Time	26/06/2025 01:34:30 PM

Sensor Position	Sensor S/N	Actual			F_0-value	Within Acceptance Criteria (YES / NO)?
		Average	Maximum	Minimum		
		Temp. (°C)	T (°C)	T (°C)		
1.	1011004332	122.74	122.90	121.73	30.33	YES
2.	1001009966	122.06	122.21	121.07	25.92	YES
3.	1011004203	122.68	122.81	121.63	29.90	YES
4.	1011004509	122.67	122.81	121.61	29.83	YES
5.	1011004211	122.41	122.53	121.42	28.10	YES
6.	1011004106	122.75*	122.91*	121.71	30.36	YES
7.	1011004102	122.60	122.71	121.56	29.31	YES
8.	1011004404	122.72	122.85	121.66	30.17	YES
9.	1011004338	121.90**	122.03	121.03**	24.97**	YES
10.	1011004503	122.63	122.77	121.61	29.52	YES
11.	Pressure	2.22	2.23	2.12	--	--
Average for Autoclave		122.52				

*: Maximum & Hottest.
**: Minimum & Coolest.

NOTES:

CALIBRATION TAG TECHNO AIR GATE

	Reviewed By (TAG)	Reviewed By (MEVAC)
Name	Ahmed Tarek	
Signature		
Date	30-06-2025	

Datasheet number 01.01.01.01.02: Maximum Solid distribution Cycle Final Report and Conclusion

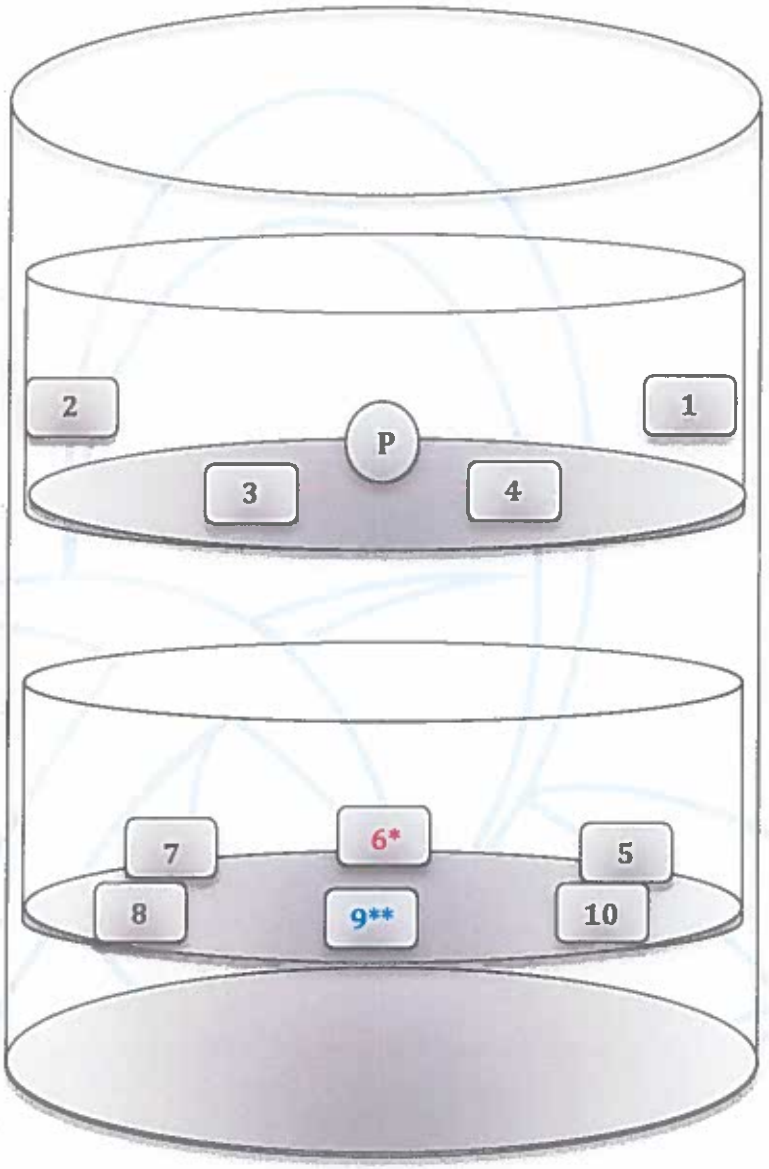
- All the registered charts, graphs, and raw data (CD) are attached in the TOP.
- The following table presents a summary of the monitored data all over the sterilization period. All obtained values are not rounded.

Results Summary			
Parameter	**Value**	**Location No.**	**Sensor S.N.**
Min. Sterilization Temp.	121.03 °C	9	1011004338
Max. Sterilization Temp.	122.91 °C	6	1011004106
Hottest Point Temperature	122.75 °C	6	1011004106
Coolest Point Temperature	121.90 °C	9	1011004338
Minimum F0-value	24.97	9	1011004338
Slowest Point	1011004338		
Equilibrium Time	45 sec		
Holding Time (Exposure Time)	20 min & 30 sec		
Plateau Period	21 min & 15 sec		

	Reviewed By (TAG)	Reviewed By (MEVAC)
Name	Ahmed Tarek	
Signature		
Date	30-06-2025	

CALIBRATION TAG TECHNO AIR GATE

Datasheet number 01.01.01.01.03: Maximum Solid distribution Cycle Layout and Sensors' Distribution



*: Hottest.
**: Coolest.

Datasheet number 01.01.01.01.04: Maximum Solid distribution Cycle Live Photos

CALIBRATION TAG TECHNO AIR GATE

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ANNEX 01.01

RESULTs DATA SHEETs

DATA SHEET 01.01.01.01

SOLID PENETRATION CYCLE TEST RESULTS

CALIBRATION TAG TECHNO AIR GATE

Datasheet number 01.01.01.02.01: Maximum Solid Penetration Cycle Test Results Data Sheets

Heat Distribution Study Data Sheet for Autoclave (M-AUX-AU014)			
Cycle No.	2 of 2		
Cycle Name	Maximum Solid Penetration Cycle		
Load Description	2 Bottles (200 ml) & silicon tools with BI		
Sterilization Temp. Setting	122 °C		
Accepted Sterilization Temp.	(121 - 125) °C		
Sterilization Time Setting	for 20 min		
Accepted Sterilization Time	NLT 20 min		
Accepted F_0-value	≥ 15 (as per customer requirement)		
Cycle Start Time	26/06/2025 02:25:00 PM	Cycle End Time	26/06/2025 04:08:15 PM
Sterilization Start Time	26/06/2025 03:03:45 PM	Sterilization End Time	26/06/2025 03:24:15 PM

Sensor Position	Sensor S/N	Actual			F_0-value	Within Acceptance Criteria (YES / NO)?
		Average Temp. (°C)	Maximum T (°C)	Minimum T (°C)		
1.	1011004332	122.58	122.67	121.76	29.18	YES
2.	1001009966	122.04	122.12	121.30	25.77	YES
3.	1011004203	122.53	122.62	121.71	28.87	YES
4.	1011004509	122.53	122.62	121.70	28.86	YES
5.	1011004211	122.33	122.40	121.64	27.56	YES
6.	1011004106	122.70*	122.80*	121.93	30.02	YES
7.	1011004102	122.55	122.63	121.77	28.98	YES
8.	1011004404	122.59	122.69	121.81	29.25	YES
9.	1011004338	121.80**	121.86	121.17**	24.36**	YES
10.	1011004503	122.57	122.69	121.80	29.12	YES
11.	Pressure	2.21	2.22	2.15	--	--
Average for Autoclave		122.42				

*: Maximum & Hottest.
**: Minimum & Coolest.

NOTES:

CALIBRATION TAG TECHNO AIR GATE

	Reviewed By (TAG)	Reviewed By (MEVAC)
Name	Ahmed Tarek	
Signature		
Date	30-06-2025	

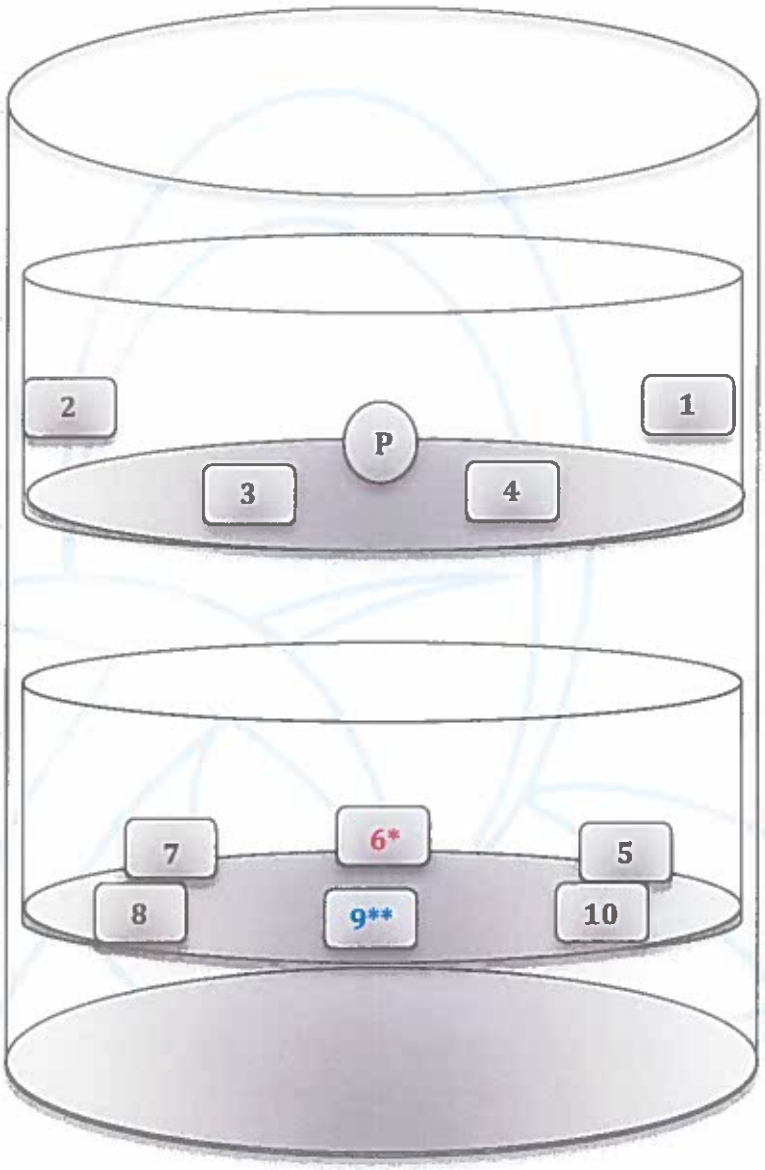
Datasheet number 01.01.01.02.02: Maximum Solid Penetration Cycle Final Report and Conclusion

- All the registered charts, graphs, and raw data (CD) are attached in the TOP.
- The following table presents a summary of the monitored data all over the sterilization period. All obtained values are not rounded.

Results Summary			
Parameter	**Value**	**Location No.**	**Sensor S.N.**
Min. Sterilization Temp.	121.17 °C	9	1011004338
Max. Sterilization Temp.	122.80 °C	6	1011004106
Hottest Point Temperature	122.70 °C	6	1011004106
Coolest Point Temperature	121.80 °C	9	1011004338
Minimum F0-value	24.36	9	1011004338
Slowest Point	1011004338		
Equilibrium Time	30 sec		
Holding Time (Exposure Time)	20 min & 30 sec		
Plateau Period	21 min		

	Reviewed By (TAG)	Reviewed By (MEVAC)
Name	Ahmed Tarek	
Signature		
Date	30-06-2025	

Datasheet number 01.01.01.02.03: Maximum Solid Penetration Cycle Layout and Sensors' Distribution



*: Hottest.
**: Coolest.

CALIBRATION TAG TECHNO AIR GATE

Datasheet number 01.01.01.02.04: Maximum Solid Penetration Cycle Live Photos

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RESULTs DATA SHEETs

DATA SHEET 01.01.02

DEVIATION REPORT

CALIBRATION TAG TECHNO AIR GATE

Datasheet Number 01.01.02.01: Deviation Report

DEVIATION REPORT

Copy 01 of 01

Test Report (N°. and Description):	**Deviation N°.: .....**
Description:	
Signature **TAG:**	Date:
Signature **MIDDLE EAST FOR VACCINES (MEVAC):**	Date:
Corrective Action:	
Person in charge to close the deviation	Expected closure date:
Signature **TAG:**	Date:
Signature QA **MIDDLE EAST FOR VACCINES (MEVAC):**	Date:
Corrective Action results	
Signature **MIDDLE EAST FOR VACCINES (MEVAC):**	Date:
Deviation successfully solved? YES____	NO____
Signature:	Date:
Signature:	Date:

CALIBRATION TAG TECHNO AIR GATE

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RESULTs DATA SHEETs

DATA SHEET 01.01.03

REFERENCE EQUIPMENT LIST AND CALIBRATION VERIFICATION

Datasheet Number 01.01.03.01: Reference Equipment List

Reference Equipment List					
Instrument Description				CALIBRATION	
No.	Instrument Description	Manufacturer/ Model	S.N.	Most recent calibration date	Calibration Due Date
1.	Data Logger	Tecnosoft s.r.l./ SterilDisk Probe	1011004332	May., 2025	Nov., 2025
2.	Data Logger	Tecnosoft s.r.l./ SterilDisk Probe	1001009966	May., 2025	Nov., 2025
3.	Data Logger	Tecnosoft s.r.l./ SterilDisk Probe	1011004203	May., 2025	Nov., 2025
4.	Data Logger	Tecnosoft s.r.l./ SterilDisk Probe	1011004509	May., 2025	Nov., 2025
5.	Data Logger	Tecnosoft s.r.l./ SterilDisk Probe	1011004211	May., 2025	Nov., 2025
6.	Data Logger	Tecnosoft s.r.l./ SterilDisk Probe	1011004106	May., 2025	Nov., 2025
7.	Data Logger	Tecnosoft s.r.l./ SterilDisk Probe	1011004102	May., 2025	Nov., 2025
8.	Data Logger	Tecnosoft s.r.l./ SterilDisk Probe	1011004404	May., 2025	Nov., 2025
9.	Data Logger	Tecnosoft s.r.l./ SterilDisk Probe	1011004338	May., 2025	Nov., 2025
10.	Data Logger	Tecnosoft s.r.l./ SterilDisk Probe	1011004503	May., 2025	Nov., 2025
11.	Data Logger	Tecnosoft s.r.l./ PressureDisk 05	3501009327	May., 2025	Nov., 2025

	Reviewed By (TAG)	Reviewed By (MEVAC)
Name	Ahmed Tarek	
Signature		
Date	30-06-2025	

CALIBRATION TECHNO AIR GATE

Datasheet Number 01.01.03.02: Sensors Pre-Calibration Check

Reference Equipment List					
Equipment Description	Manufacturer	Model	S.N.	Most recent calibration date	Calibration Due Date
Pt-100 with digital indicator	GREISINGER	GMH 3710	32403245/116	Mar., 2025	Mar., 2026

Pre-Calibration Check Results				
No.	Sensors S.N.	Error @ 100 °C (°C)	Error @ 121 °C (°C)	Error @ 130 °C (°C)
1.	1011004332	-0.08	0.11	0.07
2.	1001009966	0.13	0.26	0.22
3.	1011004203	0.19	0.13	0.05
4.	1011004509	0.39	0.19	0.22
5.	1011004211	0.46	0.48	0.43
6.	1011004106	-0.01	0.14	0.11
7.	1011004102	-0.04	0.14	0.09
8.	1011004404	0.45	0.24	0.29
9.	1011004338	0.03	0.16	0.27
10.	1011004503	0.15	0.26	0.20

CALIBRATION TAG TECHNO AIR GATE

	Reviewed By (TAG)	Reviewed By (MEVAC)
Name	Ahmed Tarek	
Signature		
Date	30-06-2025	

Datasheet Number 01.01.03.03: Sensors Post-Calibration Check

Reference Equipment List					
Equipment Description	Manufacturer	Model	S.N.	Most recent calibration date	Calibration Due Date
Pt-100 with digital indicator	GREISINGER	GMH 3710	32403245/116	Mar., 2025	Mar., 2026

Post-Calibration Check Results				
No.	Sensors S.N.	Error @ 100 °C (°C)	Error @ 121 °C (°C)	Error @ 130 °C (°C)
1.	1011004332	-0.07	0.12	0.08
2.	1001009966	0.19	0.32	0.28
3.	1011004203	0.23	0.17	0.09
4.	1011004509	0.36	0.16	0.19
5.	1011004211	0.51	0.53	0.48
6.	1011004106	-0.05	0.10	0.07
7.	1011004102	-0.06	0.12	0.07
8.	1011004404	0.48	0.27	0.32
9.	1011004338	0.07	0.20	0.31
10.	1011004503	0.20	0.31	0.25

	Reviewed By (TAG)	Reviewed By (MEVAC)
Name	Ahmed Tarek	
Signature		
Date	30-06-2025	

CALIBRATION TAG TECHNO AIR GATE

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RESULTs DATA SHEETs

DATA SHEET 01.01.04

LIST OF ATTACHEMENTS

CALIBRATION TAG TECHNO AIR GATE

Datasheet Number 01.01.04.01: List of Attachments

List of Attachments		
Attachment No.	Description	Location
01.02.01.01	Maximum Solid Distribution Cycle Printouts	Annex-01.02 (Turn Over Package)
01.02.02.01	Maximum Solid Penetration Cycle Printouts	Annex-01.02 (Turn Over Package)
01.02.01.02	Raw Data (on CD)	Annex-01.02 (Turn Over Package)
01.02.01.03	Inspection Label	Annex-01.02 (Turn Over Package)
01.02.01.04	Reference Equipment Calibration Certificates	Annex-01.02 (Turn Over Package)
01.02.01.05	Inspection Certificate	Annex-01.02 (Turn Over Package)

	Reviewed By (TAG)	Reviewed By (MEVAC)
Name	Ahmed Tarek	
Signature		
Date	30-06-2025	

CALIBRATION TAG TECHNO AIR GATE

FINAL REVIEW AND APPROVAL

The review of the test execution and the relevant raw data allow concluding that the performance qualification has been concluded:

Comply ☒ Comply with Deviation ☐ Doesn't Comply ☐

NOTES:

	Name	Signature	Title	Company	Date
Approved by	Salma Salah	Salma Salah	T.O.E.	TAG	30-06-2025
Approved by	Ahmed Mohamed	Ahmed	P.E.	TAG	30-06-2025
Approved by	Noha Essam	Noha Essam	SR. T.O.E	TAG	30-06-2025
Approved by	Ahmed Tarek		T.M.	TAG	30-06-2025
Approved by					
Approved by					
Approved by					

CALIBRATION TAG TECHNO AIR GATE