



VIVALINE MEDICAL

PRIMARY PRODUCTION CLEANROOM 1

CLEANROOM VALIDATION TO SABS / ISO 14644 - 1 : 2015

AND SABS / ISO 14644 - 3 : 2019 STANDARDS



ΜΑΤΙΧ

SAXENBURG PARK 2 Buketraube St, Blackheath CAPE TOWN Tel: 021 905-0055 Fax: 086 660-4025

CLEANROOM VALIDATION CERTIFICATE				
CLIENT	TEST LOCATION	DOCUMENT NUMBER		
	PRIMARY PRODUCTION ROOM: CLEANROOM 1	SO154191		
Unit 3 Delson Park. Somerset West Business Park Somerset West. Cape Town, 7135		28 February 2024		

CUSTOMER	SUPPLIER	SUPPLIER
CLIENT CO-ORDINATOR	VALIDATION CO-ORDINATOR	AUDITED BY
	Filta-Matix (Pty) Ltd	Filta-Matix (Pty) Ltd
	A	
	bwaldegrave	msmit
LINDSAY J. CURRAN	BRUCE WALDEGRAVE	MARINDA SMIT

DESCRIPTION OF CONTENTS

This is to certify that the facility / System covered by this report has been tested in accordance with: SABS / ISO 14644 -1 : 2015

VALIDATION REPORT						
CLASSIFICATION OF AIR CLEANLINESS BY PARTICLE CONCENTRATION						
FACILITY NAME	ACCEPTANCE CRITERIA (ISO CLASS)	TEST METHOD	TEST PROCEDURE	TEST Apparatus	TEST RESULTS	Rectification Action
CLEANROOM 1	ISO CLASS 8	ANNEX A	ANNEX A.5	ANNEX A.2	PASS	NO RECTIFICATION ACTIONS REQUIRED



No rectification action needed Minor rectification action needed

Major rectification action needed

	VALIDATION PERIOD	
Non Uni-directional Flow : Uni-directional Flow :	28 FEBRUARY 2024 - 28 FEBRUARY 2025 N/A	(12 Months) (6 Months)
FILTA		SAXENBURG PARK 2 Buketraube St, Blackheath CAPE TOWN Tel: 021 905-0055 Fax: 086 660-4025
		(et. 021 903-0035 Fax, 066 600-4023

CLEANROOM VALIDATION CERTIFICATE				
CLIENT	TEST LOCATION	DOCUMENT NUMBER		
Unit 3 Delson Park. Somerset West Business Park Somerset West. Cape Town, 7135	PRIMARY PRODUCTION ROOM: CLEANROOM 1	SO154191 28 February 2024		

CUSTOMER	SUPPLIER	SUPPLIER
CLIENT CO-ORDINATOR	VALIDATION CO-ORDINATOR	AUDITED BY
	Filta-Matix (Pty) Ltd	Filta-Matix (Pty) Ltd
		_
	bwaldegrave	msmit
LINDSAY J. CURRAN	BRUCE WALDEGRAVE	MARINDA SMIT

DESCRIPTION OF CONTENTS

This is to certify that the facility / System covered by this report has been tested in accordance with: SABS / ISO 14644 - 3 :2019

VALIDATION REPORT					
PROCEDURE FOR NON-UNIDIRECTIONAL AIRFLOW TESTING					
FACILITY NAME	TEST METHOD	TEST PROCEDURE	TEST Apparatus	TEST RESULTS	Rectification Action
CLEANROOM 1	ANNEX B.2	ANNEX B.2.3.3	ANNEX C.3.2.2	PASS	NO RECTIFICATION ACTIONS REQUIRED



No rectification action needed Minor rectification action needed

Major rectification action needed

VALIDATION PERIOD				
Non Uni-directional Flow : Uni-directional Flow :	28 FEBRUARY 2024 - 28 FEBRUARY 2025 N/A	(12 Months) (6 Months)		
FILTA		SAXENBURG PARK 2 Buketraube St, Blackheath CAPE TOWN Tel: 021 905-0055 Fax: 086 660-4025		

CLEANROOM VALIDATION CERTIFICATE				
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Unit 3 Delson Park. Somerset West Business Park Somerset West. Cape Town, 7135	PRIMARY PRODUCTION ROOM: CLEANROOM 1	SO154191 28 February 2024		

CUSTOMER	SUPPLIER	SUPPLIER
CLIENT CO-ORDINATOR	VALIDATION CO-ORDINATOR	AUDITED BY
	Filta-Matix (Pty) Ltd	Filta-Matix (Pty) Ltd
	lucidada	the second s
	on accord care	MIMM
LINDSAY J. CURRAN	BRUCE WALDEGRAVE	MARINDA SMIT

DESCRIPTION OF CONTENTS

This is to certify that the facility / System covered by this report has been tested in accordance with: SABS / ISO 14644 - 3 :2019

VALIDATION REPORT					
PROCEDURE FOR AIR PRESSURE DIFFERENCE TEST					
FACILITY NAME	TEST METHOD	TEST PROCEDURE	TEST Apparatus	TEST RESULTS	Rectification Action
CLEANROOM 1	ANNEX B.1	ANNEX B.1.2	ANNEX C.2.2	PASS	NO RECTIFICATION ACTIONS REQUIRED



No rectification action needed Minor rectification action needed

Major rectification action needed

VALIDATION PERIOD					
Non Uni-directional Flow : Uni-directional Flow :	28 FEBRUARY 2024 - 28 FEBRUARY 2025 N/A	(12 Months) (6 Months)			
FILTA		SAXENBURG PARK 2 Buketraube St, Blackheath CAPE TOWN Tel: 021 905-0055 Fax: 086 660-4025			
		Tel: 021 905-0055 Fax: 086 660-4025			





VIVALINE MEDICAL PRIMARY AREA - CLEANROOM 1

	AIR CLEANLINESS CLA	SSIFICATION TEST RESULTS	
	CLEANROOM 1 (NON-	UNIDIRECTIONAL AIRFLOW)	
Date of Test :	2024/02/28	Time :	10:07:07
Period / Sample :	1 MIN	Occupancy State :	AT REST
Volume / Sample :	M ³ H	Calibration Date :	2024/02/13
Anemometer :	TESTO	Calibration Due :	2025/02/13
Model :	420	Calibration Certificate No :	CAL-G-N-P-240212L03
Serial no :	50604054/1217	Testing Standard :	ISO 14644-3: 2019

TEST METHOD

The cleanroom is tested in accordance with ISO 14644-3:2019 "Test Methods". The air volume flow rate is measured using an airflow capture hood with a measuring device. The opening of airflow capture hood is placed completely over the entire filter or diffuser, and the face of the hood is seated against a flat surface to prevent air bypass and inaccurate readings. The airflow capture hood is fitted with a measuring device, and therefore the air volume flow rate at each final filter or diffuser is measured directly at the discharge end of the hood.

1. AIRFLOW DATA



Airflow Direction	Positive Pressure
Extract Air (mm):	300x300/290x245
Supply Air (mm):	590x590
Height of Facility (m):	2,38
Area (m²):	42,24
Volume (m³):	100,53
Minimum Recommended Air Changes	20 ACH
Relative Humidity (%) Requirement	N/A
Temperature (°C) Requirement	N/A

	SA 1	SA 2	SA 3	SA 4	SA 5	SA 6	SA 7	SA 8	TOTAL
Supply Air Volume (m²/h)	620	645	555	195	572	482	N/A	N/A	3069

	EA 1	EA 2	EA 3	EA 4	EA 5	EA 6	EA 7	EA 8	EA 9
Extract Air Volume (m³/h)	466	303	288	209	N/A	N/A	N/A	N/A	1266
	Air Changes Per Hour: 30,53								
Conclusion: Room total a	ir changes pe essure differe	er hour is abo ences to adjac	ve design spe ent rooms is	ecification and within design	d is therefore specificatior	compliant. Is and is there	efore complia	nt.	Air
FILTA								Saxenbu Cnr Zinfandel & Blackheath Tel: 021 905-0055	rrg Park 2 8 Buketraube St, , Cape Town Fax: 086 660-4025

PARTICLE COUNT TEST RESULTS

CLEANROOM 1 (NON-UNIDIRECTIONAL AIRFLOW)

Date of Test :	2023/03/03
Period / Sample :	1 MIN
Volume / Sample :	CFM
LSAPC :	CLIMET
Model :	CI-150T
Serial no :	68439

Time :	13:40:59
Occupancy State :	AT REST
Calibration Date :	2023/03/08
Calibration Due :	2024/03/08
Calibration Certificate No :	UK01-37366
Testing Standard :	ISO 14644 - 1: 2015

ACCEPTANCE CRITERIA:

The cleanroom is required to meet the ISO 14644-1:2015 "Classification of air cleanliness by particle concentration", ISO Class 8 classification in an 'At Rest' state. The room is deemed to have met the specified air cleanliness classification if the averages of the particle concentrations (cumulative) measured at each of the locations do not exceed the concentration limits specified in the table included on the report. Each location is treated independently, and no assumption is made that counts follow the same normal distribution across the room

TEST METHOD:

The particle counter is set up in accordance with the manufacturer's instructions including a zero-count check. The sampling probe is positioned into the airflow, or vertically upwards. After achieving normal conditions for the specified occupancy state, the air is sampled. A determined volume of air is sampled at each location.

	Targ	et ISO Class : 8		
Cumulative Particle Count = >	0,3	0,5	1,0	5,0
Maximum permissible Counts	N/A	3520000	N/A	29300

Sampling Locations	Х ⊧ ≥ 0.5µm (counts per 28.3l)	Location sample average (counts per 28.3!)	Location concentration average (counts per m ³ = location average x 35.3147)	ISO Class 8 limit for 0.5µm particle size	ISO CLASS	Pass/Fail
1	4999	4999	176538,2	3520000	8	PASS
2	14375	14375	507648,8	3520000	8	PASS
3	15647	15647	552569,1	3520000	8	PASS
4	13730	13730	484870,8	3520000	8	PASS
5	9202	9202	324965,9	3520000	8	PASS
6	13298	13298	469614,9	3520000	8	PASS
7	12563	12563	443658,6	3520000	8	PASS
8	12900	12900	455559,6	3520000	8	PASS
9	9360	9360	330545,6	3520000	8	PASS
10	10003	10003	353252,9	3520000	8	PASS

Sampling Locations	× i ≥ 5.0μm (counts per 28.3l)	Location sample average (counts per 28.3l)	Location concentration average (counts per m³ = location average x 35.3147)	ISO Class 8 limit for 5.0μm particle size	ISO CLASS	Pass/Fail
1	5	5	176,6	29300	8	PASS
2	11	11	388,5	29300	8	PASS
3	11	11	388,5	29300	8	PASS
4	13	13	459,1	29300	8	PASS
5	6	6	211,9	29300	8	PASS
6	9	9	317,8	29300	8	PASS
7	5	5	176,6	29300	8	PASS
8	8	8	282,5	29300	8	PASS
9	11	11	388,5	29300	8	PASS
10	4	4	141,3	29300	8	PASS

CONCLUSION

Each value of the concentration for the considered particle sizes measured is less than that of the class limit therefore, the air cleanliness by particle concentration of the cleanroom meets the required ISO class. Room complies with the design specifications and therefore passes the particle count test

Unit 1 and 2 Saxenburg Park Corner Zinfandel and Buketraube street Tel: 021 905-4025 Fax: 086 660 4025



PARTICLE COUNT SLIP

UNIT= UIUA PPR1 ISO CLASS 8 (AT 5.8 uH) PRINTED 28/82/24 18:23:84 FIRSI 28/82/24 18:22:87 LAST 28/82/24 18:22:47 PROCRAM= SAMPLE UOLUME= 1.8CF SIZE= >5.8uM AUERACE AUERACE ID #SAMPLES COUNTS CONC/CO
ISO CLASS 8 (AT 5.8 uH) PRINTED 28/82/24 18:23:84 FIRSI 28/82/24 18:87:87 LAST 28/82/24 18:22:47 PROGRAM= SAMPLE VOLUME= 1.8CF SIZE= >5.8uM AVERACE AVERACE ID #SAMPLES COUNTS CONCCT TED COUNT 1 8 8 8 8
PRINTED 28/02/24 10:23:04 FIRSI 28/02/24 10:07:07 LAST 28/02/24 10:22:47 PROGRAM= SAMPLE VOLUME= 1.0CF SIZE= >5.00M AVERACE AVERACE ID #SAMPLES COUNTS CONC/CP TED COUNT 1 0 0 0 0 0
INST 20/02/24 10:02:47 PROGRAM= SAMPLE VOLUME= 1.8CF SIZE= >5.8wM AVERAGE AVERAGE ID #SAMPLES COUNTS CONCCT TED COUNT 1 9 9 9 9
PROGRAM= SAMPLE VOLUME= 1.0CF SIZE= >5.0vm AVERAGE AVERAGE ID #SAMPLES COUNTS CONC/CO TED COUNT 9.0
SAMPLE VOLUME: 1.8CF SIZE: >5.8uM AVERACE AVERACE ID #SAMPLES COUNTS CONCCT TED COUNT 1 9 9 9 9 9
SIZE= >5.80H AVERACE AVERACE ID #SAMPLES COUNTS CONC/CP TERD COUNT 1 9.8 9.9
ID #SAMPLES COUNTS CONC/CP
2180 1008 1 88
DATHT 4 1 5 6 194 4
DAINT 2 1 11 8 388 5
POINT 2 1 11.6 388.5
POINT 4 1 13.8 459.1
POINI 5 1 6.8 211.9
POINT 6 1 9.8 317.8
POINT 7 1 5.0 176.6
POINT 8 1 8.0 282.5
POINI 9 1 11.8 388.5
POINT 10 1 4.6 141.3
ISO 14644-1 REPORT
PASS
UNIT= UIUA PPR1
ISO CLASS 8 (AT 8.5 uM)
PRINIED 28/02/24 10:23:04
FIRSI 28/02/24 10:07:07
LASI 28/02/24 10:22:47
PROGRAM=
SAMPLE VOLUME= 1.8CF
SIZE=)0.5uM AVERACE AVERAGE
ID #SAMPLES COUNTS CONC/CM
ZERO COUNT 1. 8.8 8.8
POINT 1 4999.0 176538.0
POINT 2 1 14375.0 507648.3
POINT 3 1 15647.8 552568.6
POINT 4 1 13730.8 484870.4
POINT 5 1 9282.8 324965.6
POINT 6 1 13298.8 469614.4
TVINI / 1 16303.6 443638.6 DAINT 0 3 13608 6 450304 4
POINT 9 1 9268 8 328545 2
POINT 10 1 1000.0 330343.3
10101 10 1 1000010 3323210



ΜΑΤΙΧ

CALIBRATION CERTIFICATE:

LIGHT SCATTERING AIRBOURNE PARTICLE COUNTER

The instrument under test National Standards or are measurements made at th calibration.	was calibrated against derived by approved le time of test and no	standards which are either traceab ratio techniques. The results ref t to the instruments ability to mai	ole to er to intain
Prepared For:	Filta-Matix (Pty) Ltd JI 23 Basalt Street	HB	
	Gauteng 1450	n, 1450	
Service Report No.:	UK01-37366		
Make:	Climet		
Model:	CI-150t		
Serial No.:	068439		
Date of Calibration:	8-Mar-23		
Calibration Due Date:	8-Mar-24		
Calibration Procedure:	OSL-10034		
The instrument complies w	ith the specification at	the measured points.	
Comments: None			
Calibration Performed By:	Matthew Tilly	Document Approved By:	
Date:	8-Mar-23	Service Manager 🛛 Technical Projects Mana	ager A
Signature: P.P.	\downarrow	Engineer AMan	N



MATIX

CALIBRATION CERTIFICATE:

AIRFLOW VOLUME CAPTURE HOOD (BALOMETER)

Testo Sout	h Africa	(Pty) Ltd		Be	sure. t	esto
Calibration Certi	ficate	CAL-G-N-P-24 Certificate n	0212L03 number		Page 1 of 2	2
		A L - 6 - N -	P - 2 6 0 2 1 2	103.		
Manufacturer	INSTRUM	ENI				
Type	10510					
Part No	420	20				
Serial No.	50604054	1217				
oonarito.	50004054/	1217				
Location:		Unit 1 Glenea Corner Braan Glen Marais Kempton Par 1630	agle Office Park nbos Road & Mo k	nument Road		
Company Name:		Filta-Matix (P	ty) Ltd			
Address:		23 Basalt Ste Alrode Ext 7 1450 Albertor	et n			
Internal Order No:		ID 32737				
Date of calibration:		12/02/2024		RUBRATIO	STO PRATOP	
Recommended re-c	alibration date:	February 202	5.	b 13 Fi	B 2024	
Was the instrument	adjusted?	NO		KEMPT	ON PARK	
The reported expande evel of confidence of principles defined in the The calibration certific aboratory.	d uncertainty is approximately 9 le GUM, guide to ate may not be r	based on a standa 5%, the uncertainty o uncertainty of me eproduced other th	rd uncertainty multi y of measurement h pasurement, ISO, G han in full and with t	blied by a coverage as been estimated eneva, 1993. he permission of Te	factor k=2 provid n accordance wit sto South Africa	ing a h the
			·····			
TB	<u>مالا</u>		que			
alibrated by: Itumele	ng Bolofo		Signatory: Moloti	Talane		
	Phone JHB: +27 1	L 380 8060 CT: +27 21 Reg No. 2	300 3260, <u>info@testo.c</u> 015/403399/07	0.za, www.testo.co.za		



ΜΑΤΙΧ

CALIBRATION CERTIFICATE: DIGITAL PRESSURE METER(MANOMETER)

Testo South Africa (Pty) Ltd		Be sure. testo	
Calibration Certificate	CAL-G-N-P-240207L08 Certificate number	Page 1 of 2	
INS	TRUMENT		
Manufacturer	Testo		
Туре	510		
Part No. 0/	563 0510		
Serial No. 514	87727/909		
Location:	Unit 1 Gleneagle Office Park Corner Braambos Road & Moı Glen Marais Kempton Park 1630	nument Road	
Company Name:	Filta-Matix (Pty) Ltd		
Address:	23 Basalt Street Alrode Ext 7 1450 Alberton		
Internal Order No:	ID 32737	BRATION LABORA	
Date of calibration:	07 /02/2024	SOUTH AFRICA	
Recommended re-calibration date	E February 2025.	1 3 FEB 2024	
Was the instrument adjusted?	NO	ATEMPTON PARK	
The reported expanded uncertainty is level of confidence of approximately f principles defined in the GUM, guide	based on a standard uncertainty multip 95%, the uncertainty of measurement has to uncertainty of measurement, ISO, Gr	plied by a coverage factor k=2 providing a as been estimated in accordance with the eneva, 1993.	
The calibration certificate may not be Laboratory.	reproduced other than in full and with the	he permission of Testo South Africa	
Floto	the	— .	
Calibrated by: Itumeleng Bolofo	Signatory: Moloti T	Falane	
Phone JH8: +27	11 380 8060 CT: +27 21 300 3260, info@testo.co Reg No. 2015/403399/07	0.za, www.testo.co.za	