

VALIDATION CLEAN ROOM AND CONTROLLED AREAS

According to UNI EN ISO 14644-1/2, UNI EN ISO 14698-1/2

REPORT N. 2506-15

Customer: **VSM Assembly**
9900 Körmend - Rákóczi utca 31 (Ungheria)

TIME SCHEDULE



Acceptance N.: 15-2056
Test location 9900 Körmend - Rákóczi utca 31 (Ungheria)
Start test date: 22/06/2015
End test date: 30/06/2015
Operator: Dr. M. Gozzi

TEST LABORATORY

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REFERENCE DOCUMENTS

- UNI EN ISO 14644-1/2: 2001 Cleanrooms and associated controlled environments – Classification air cleanliness
- Internal Procedure PT 02 "Particulate contamination control in Clean Room"
- Annex 1 - Mapping sampling points

Date	Prepared by: Dr. M. Gozzi	Verified and Approved by: Dr. Renzo Coronati
30/07/2015		

This test report is digitally signed by Dr. Renzo Giovanni Coronati.
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INSTRUMENTS AND EQUIPMENT

Instrument	Code	Calibration certificate		Frequency calibration
		Certificate nr.	Calibrat. date	
Particle Counter Met One 3423 LLD	SPR 028	AR-0087-15 (AM Instruments)	09/02/2015	1 /year + 1 month
Probe T e UR% Met One 3423 LLD	SS 078	Internal calibration	25/05/2015	1 /year + 1 month
Air sampler SAS super 180	SPR 027	086 FI (VWR International PBI)	26/02/2015	1 /year + 1 month
Digital Manometer TESTO 512	SPR 017	1239P14 (EMIT LAS)	20/11/2014	1 /year + 1 month
Anemometer	SS 069	TST 5804/2011 MI (Testo)	22/12/2011	1/5 years + 1 month

PURPOSE

The purpose of this validation is to verify that the operating parameters of the Clean Room and controlled area are in conformity with the project technical specifications agreed between the Commitment and Supplier of the Clean Room. The validation process requires to perform the following tests:

1. **Airborne micro particles contamination**
2. **Airborne and surface microbial contamination of critical working areas and surfaces**
3. **Numbers of air changes per hours in clean room**
4. **Smoke Test to verify air flow direction**
5. **Overpressure.**

SAMPLING CONDITIONS

Controlled Room	Surface (m ²)	Sampling points (particulate)	No. operators	TEMP. (°C)	RH (%)	ΔP (mmH ₂ O)	Operating conditions
CLEAN ROOM	45	8	2 technicians + 22 operators	19,3	62,9	/	operational
AIR LOCK 1	2,5	2	2 technicians	20,1	61,8	/	operational
AIR LOCK 2	2,5	2	2 technicians	21,0	58,0	/	operational

1. PARTICULATE CONTROL

Purpose

The aim of the test is to define the micro-particulate contamination of a controlled environment classified according to UNI EN ISO 14644-1. For the classification and limits the particles having dimensions of 0,5 μm are considered according to the class definition by the rule UNI EN ISO 14644-1 that forecast to indicate one or more diameters of the particles in the range 0,1μm - 5μm without to fix a specific diameter. In particular the point 2.1.4 of the rule says: "The dimensions of the considered particles (values limit lower) applicable to the definition are limited in the range included between 0,1 μm and 5 μm". The point 3.3 says: "the dimension or dimensions of the particles considered for which is measured the concentration, have to be agreed between customer and supplier".

Operating methods

The operative modalities are reported on UNI EN ISO 14644-1 and in the table below.

Time sampling at each point	60 sec
Volume of air sampled in each point	0,050 m ³
Sampling	anisocinetic
Position probe	to 1 meter in height from the floor

Acceptance criteria

The Clean Room and the controlled areas are considered conforming when all results are less than the UNI EN ISO 14644-1 limit defined for each type of class.

Results interpretation (UNI EN ISO 14644-1)

Clean Room classification UNI EN ISO 14644-1		Alert and Action level	
Class	N. max particles $\varnothing \geq 0,5 \mu\text{m}/\text{m}^3$	Alert level $\varnothing \geq 0,5 \mu\text{m}/\text{m}^3$	Action level $\varnothing \geq 0,5 \mu\text{m}/\text{m}^3$
ISO 9	35.200.000	28.160.000	35.200.000
ISO 8	3.520.000	2.816.000	3.520.000
ISO 7	352.000	281.600	352.000
ISO 6	35.200	28.160	35.200
ISO 5	3.520	2.816	3.520
ISO 4	352	282	352
ISO 3	35	28	35
ISO 2	4	3	4

Summary results

Controlled room	Project class	Alert level $\varnothing \geq 0,5 \mu\text{m}/\text{m}^3$	Average $\varnothing \geq 0,5 \mu\text{m}/\text{m}^3$	Class found	Result
CLEAN ROOM	ISO Class 8	2.816.000	449.207,0	ISO Class 8	Pass
AIR LOCK 1	ISO Class 8	2.816.000	607.702,3	ISO Class 8	Pass
AIR LOCK 2	ISO Class 8	2.816.000	727.875,9	ISO Class 8	Pass

The detailed results obtained from each controlled room are reported in the next pages.

-- ISO 14644-1 STATISTICHE --				-- ISO 14644-1 STATISTICHE --				-- ISO 14644-1 STATISTICHE --			
MEDIA PARTICELLE/METRO CUBO				MEDIA PARTICELLE/METRO CUBO				MEDIA PARTICELLE/METRO CUBO			
N/S: 060701130				N/S: 060701130				N/S: 060701130			
POSIZIONI: 008				POSIZIONI: 002				POSIZIONI: 002			
POSIZIONE ID:	008	POSIZIONE ID:	003	POSIZIONE ID:	010	POSIZIONE ID:	012				
NOME POSIZIONE:	8	NOME POSIZIONE:	3	NOME POSIZIONE:	10	NOME POSIZIONE:	12				
2015-06-22	09.02.25	2015-06-22	08.54.22	2015-06-22	09.07.58	2015-06-22	09.19.28				
PORTATA:	50,00LM	PORTATA:	50,00LM	PORTATA:	50,00LM	PORTATA:	50,00LM				
VOLUME:	50,00L	VOLUME:	50,04L	VOLUME:	50,02L	VOLUME:	50,02L				
TEMPERATURA:	19,9 C	TEMPERATURA:	19,2 C	TEMPERATURA:	20,2 C	TEMPERATURA:	21,0 C				
UMIDITA' RELATIVA:	59,0%	UMIDITA' RELATIVA:	64,2%	UMIDITA' RELATIVA:	62,5%	UMIDITA' RELATIVA:	58,7%				
VEL. ARIA:	0,0mm/Sec	VEL. ARIA:	0,0mm/Sec	VEL. ARIA:	0,0mm/Sec	VEL. ARIA:	0,0mm/Sec				
CAMPIONI:	1	CAMPIONI:	1	CAMPIONI:	1	CAMPIONI:	1				
DIM. (um)	CUM.	DIFF.	DIM. (um)	CUM.	DIFF.	DIM. (um)	CUM.	DIFF.			
0,3	536700,0	185460,0	0,3	887889,7	351658,7	0,3	1067273,1	478628,5			
0,5	351240,0	157820,0	0,5	536231,0	242945,6	0,5	588644,5	268172,7			
1,0	193420,0	125340,0	1,0	293285,4	196183,1	1,0	320471,8	208456,6			
3,0	68080,0	34920,0	3,0	97102,3	50339,7	3,0	112015,2	55617,8			
5,0	33160,0	23440,0	5,0	46762,6	31834,5	5,0	56397,4	39524,2			
10,0	9720,0	9720,0	10,0	14928,1	14928,1	10,0	16873,3	16873,3			
POSIZIONE ID:	007	POSIZIONE ID:	002	POSIZIONE ID:	009	POSIZIONE ID:	011				
NOME POSIZIONE:	7	NOME POSIZIONE:	2	NOME POSIZIONE:	9	NOME POSIZIONE:	11				
2015-06-22	09.00.11	2015-06-22	08.52.36	2015-06-22	09.06.39	2015-06-22	09.18.11				
PORTATA:	50,00LM	PORTATA:	50,00LM	PORTATA:	50,00LM	PORTATA:	50,00LM				
VOLUME:	50,05L	VOLUME:	50,03L	VOLUME:	50,00L	VOLUME:	50,00L				
TEMPERATURA:	19,7 C	TEMPERATURA:	18,9 C	TEMPERATURA:	20,1 C	TEMPERATURA:	21,0 C				
UMIDITA' RELATIVA:	61,2%	UMIDITA' RELATIVA:	64,8%	UMIDITA' RELATIVA:	61,0%	UMIDITA' RELATIVA:	57,3%				
VEL. ARIA:	0,0mm/Sec	VEL. ARIA:	0,0mm/Sec	VEL. ARIA:	0,0mm/Sec	VEL. ARIA:	0,0mm/Sec				
CAMPIONI:	1	CAMPIONI:	1	CAMPIONI:	1	CAMPIONI:	1				
DIM. (um)	CUM.	DIFF.	DIM. (um)	CUM.	DIFF.	DIM. (um)	CUM.	DIFF.			
0,3	509350,7	184355,7	0,3	857465,5	269198,5	0,3	1245200,0	618440,0			
0,5	324995,0	149570,4	0,5	588267,0	288207,1	0,5	626760,0	295280,0			
1,0	175424,6	118541,5	1,0	300060,0	203737,8	1,0	331480,0	221700,0			
3,0	56883,1	29610,4	3,0	96322,2	47571,5	3,0	109780,0	56220,0			
5,0	27272,7	18961,0	5,0	48750,7	33899,7	5,0	53560,0	38520,0			
10,0	8311,7	8311,7	10,0	14851,1	14851,1	10,0	15040,0	15040,0			
POSIZIONE ID:	006	POSIZIONE ID:	001	MEZZO DELLE MEDIE		MEZZO DELLE MEDIE					
NOME POSIZIONE:	6	NOME POSIZIONE:	1	DIM. (um)	CUM.	DIFF.	DIM. (um)	CUM.	DIFF.		
2015-06-22	08.58.30	2015-06-22	08.51.08	0,3	1156236,5	548534,3	0,3	6455792,2	5727916,3		
PORTATA:	50,10LM	PORTATA:	50,00LM	0,5	607702,3	281726,4	0,5	727875,9	455951,5		
VOLUME:	50,06L	VOLUME:	50,03L	1,0	325975,9	215078,3	1,0	271924,4	177774,2		
TEMPERATURA:	19,6 C	TEMPERATURA:	18,4 C	3,0	110897,6	55918,9	3,0	94150,2	46540,3		
UMIDITA' RELATIVA:	61,5%	UMIDITA' RELATIVA:	65,7%	5,0	54978,7	39022,1	5,0	47609,9	32293,2		
VEL. ARIA:	0,0mm/Sec	VEL. ARIA:	0,0mm/Sec	10,0	15956,6	15956,6	10,0	15316,8	15316,8		
CAMPIONI:	1	CAMPIONI:	1	DIM. (um)	DEV STD.	ERRORE DVS	DIM. (um)	DEV STD.	ERRORE DVS		
DIM. (um)	CUM.	DIFF.	DIM. (um)	CUM.	DIFF.	DIM. (um)	DEV STD.	ERRORE DVS			
0,3	531062,7	203296,0	0,3	937057,8	366060,4	0,3	125813,3	88963,5			
0,5	327766,7	138993,2	0,5	570997,4	285228,9	0,5	26951,7	19057,7			
1,0	188773,5	125209,7	1,0	285768,5	198281,0	1,0	7784,0	5504,1			
3,0	63563,7	33779,5	3,0	87487,5	43354,0	3,0	1580,5	1117,6			
5,0	29784,3	20974,8	5,0	44133,5	28403,0	5,0	2006,4	1418,7			
10,0	8809,4	8809,4	10,0	15730,6	15730,6	10,0	1296,3	916,6			
POSIZIONE ID:	005	MEZZO DELLE MEDIE		MEZZO DELLE MEDIE							
NOME POSIZIONE:	5	DIM. (um)	CUM.	DIFF.	DIM. (um)	CUM.	DIFF.				
2015-06-22	08.57.00	0,3	714284,5	265077,5	0,3	1716706,3	831102,7				
PORTATA:	50,10LM	0,5	449207,0	210250,0	0,5	727766,0	521900,2				
VOLUME:	50,08L	1,0	238957,0	160514,9	1,0	360651,7	273130,4				
TEMPERATURA:	19,4 C	3,0	78442,1	39723,2	3,0	117938,4	89006,8				
UMIDITA' RELATIVA:	63,1%	5,0	38718,9	26371,4	5,0	63916,7	44274,9				
VEL. ARIA:	0,0mm/Sec	10,0	12347,5	12347,5	10,0	21731,4	14409,1				
CAMPIONI:	1	DIM. (um)	DEV STD.	ERRORE DVS	DIM. (um)	DEV STD.	ERRORE DVS				
DIM. (um)	CUM.	DIFF.	DIM. (um)	DEV STD.	ERRORE DVS						
0,3	682787,5	250639,0	0,3	173900,9	61483,3						
0,5	432148,6	212100,6	0,5	108214,5	38259,6						
1,0	220047,9	150678,9	1,0	50872,1	17986,0						
3,0	69369,0	33865,8	3,0	15727,1	5560,4						
5,0	35503,2	23762,0	5,0	8270,8	2924,2						
10,0	11741,2	11741,2	10,0	3068,9	1085,0						
POSIZIONE ID:	004	MEZZO DELLE MEDIE		MEZZO DELLE MEDIE							
NOME POSIZIONE:	4	DIM. (um)	CUM.	DIFF.	DIM. (um)	CUM.	DIFF.				
2015-06-22	08.55.42	0,3	771962,4	309952,0	0,3	771962,4	309952,0				
PORTATA:	50,00LM	0,5	462010,4	207134,3	0,5	462010,4	207134,3				
VOLUME:	50,04L	1,0	254876,1	166147,1	1,0	254876,1	166147,1				
TEMPERATURA:	19,3 C	3,0	88729,0	44344,5	3,0	88729,0	44344,5				
UMIDITA' RELATIVA:	64,4%	5,0	44384,5	29696,2	5,0	44384,5	29696,2				
VEL. ARIA:	0,0mm/Sec	10,0	14688,2	14688,2	10,0	14688,2	14688,2				
CAMPIONI:	1	DIM. (um)	DEV STD.	ERRORE DVS	DIM. (um)	DEV STD.	ERRORE DVS				
DIM. (um)	CUM.	DIFF.	DIM. (um)	DEV STD.	ERRORE DVS						

Conclusions

The results comply with the requirements of the standard ISO 14644-1.

In **Annex 01** is reported the mapping sampling points airborne particulate contamination controls

2. MICROBIOLOGICAL CONTROL

Purpose

The purpose of this study is to measure the airborne microbial contamination and surface microbial contamination inside the clean room and controlled areas for the production and packaging of medical devices.

Operating Methods

The operative modalities are reported on UNI EN ISO 14698-1/2, PT03 and in the table below.

Airborne microbial contamination with active sampling:	<ul style="list-style-type: none"> ➤ Air volume sampled by SAS: 100 litres ➤ SAS Position: 1 m from the floor
Surface microbial contamination of working surfaces, floor, hands, garments, containers:	<ul style="list-style-type: none"> ➤ TSA Contact plate Ø 55 mm

Acceptance criteria

C.F.U. (Colony Forming Units) counted in each plate must comply with the limit defined for each cleaning class.

Results

CLEAN ROOM				
AIRBORNE BIOCONTAMINATION				
Sampling position	Total contamin. (C.F.U./m ³)	Alert level (C.F.U./m ³)	Action level (C.F.U./m ³)	Result
1A	120	160	200	Pass
2A	150	160	200	Pass
3A	130	160	200	Pass
4A	90	160	200	Pass
5A	150	160	200	Pass
6A	140	160	200	Pass
SURFACE BIOCONTAMINATION				
Sampling position	Total contamin. (C.F.U./plate)	Alert level (C.F.U./plate)	Action level C.F.U./plate)	Result
1S: Operator 1 hand	15	40	50	Pass
2S: Operator 2 hand	19	40	50	Pass
3S: Operator 3 shirt	14	40	50	Pass
4S: Green table surface	25	40	50	Pass
5S: White table surface	4	40	50	Pass
6S: Green tank inside	2	40	50	Pass
7S: Floor	12	40	50	Pass
8S: Wall	1	40	50	Pass
AIR LOCK 1				
AIRBORNE BIOCONTAMINATION				
Sampling position	Total contamin. (C.F.U./m ³)	Alert level (C.F.U./m ³)	Action level (C.F.U./m ³)	Result
7A	150	160	200	Pass
AIR LOCK 2				
AIRBORNE BIOCONTAMINATION				
Sampling position	Total contamin. (C.F.U./m ³)	Alert level (C.F.U./m ³)	Action level (C.F.U./m ³)	Result
8A	120	160	200	Pass

Conclusion

The results comply with the requirements of the standard ISO 14698-1 and with the agreed limits.

In **Annex 01** is reported the mapping sampling points airborne and surface bio-contamination controls

3. AIR CHANGES/HOUR

Purpose

The aim of the test is to verify if air speed, single ranges, total ranges and number of changes are in accordance with the manufacturing specifications defined by the supplier of the Clean Room. The balancing of the total air is calculated by the measures performed in the air ducts outlet through the blowers inlet air.

Operating method

Place the sensor of the anemometer next to the different points of the blower surface, usually in the center and in correspondence of the angles and edges, for each point perform a measure for about 10 seconds in order to allow the stabilization of the instrument, after 10 seconds perform the reading.

Results

	CLEAN ROOM							
BLOWER IDENTIFICATION	RA ₁	RA ₂	RA ₃	RA ₄	RA ₅	RA ₆	RA ₇	RA ₈
REAL BLOWER SURFACE (m ²)	0,0800	0,0800	0,0800	0,0800	0,0800	0,0800	0,0800	0,0800
EFFECTIVE BLOWER SURFACE (m ²)	0,0760	0,0760	0,0760	0,0760	0,0760	0,0760	0,0760	0,0760
SPEED (m/sec)	0,70	0,60	0,83	1,17	0,97	0,81	0,79	0,58
	0,80	0,74	0,35	1,16	1,01	0,88	1,04	0,63
	0,47	0,57	0,81	0,54	1,26	0,85	0,82	0,60
	0,92	0,82	0,78	0,88	1,15	0,87	0,77	0,73
AVERAGE SPEED (m/sec)	0,72	0,68	0,69	0,94	1,10	0,85	0,86	0,64
SINGLE FLOW (m ³ /sec)	0,05	0,05	0,05	0,07	0,08	0,06	0,06	0,05
TOTAL FLOW (m ³ /sec)	0,49							
TOTAL FLOW (m ³ /h)	1771							
ROOM VOLUME (m ³)	135							
NUMBER OF AIR CHANGES PER HOUR	13							

Conclusion

The number of air changes /hour complies with the project specifications planned for the Clean Room.

4. SMOKE TEST

Purpose

The aim of the test is to detect the direction of the air flow in the clean room and in the controlled areas and detect eventual outflow.

Operating methods

A smoke indicator vial it is used in order to detect flow and eventual dispersions. One of the vial tips is introduced in a little pump that once pushed make the smoke free so that the direction of the air flow is traced.

Results

Direction air flow	Results
From CLEAN ROOM to AIR LOCK 1	Pass
From CLEAN ROOM to AIR LOCK 2	Pass

Conclusion

Air flow direction in the Clean Room and in the controlled areas confirm a suitable overpressure of the Clean Room compared to the adjacent locals.

5. OVERPRESSURE

Purpose

The aim of the test is to verify the difference of pressure between a room and the other one for Clean Room and controlled area

Operating methods

In order to verify the overpressure it has been used a digital and gauged manometer to which hang a rubber pipe, this pipe is subsequently slipped under the door with a tip free to be placed inside the local with a bigger overpressure, wait few second in order to allow a stabilization of the instrument and than perform the reading.

Results

Rooms	ΔP (Overpressure)
CLEAN ROOM – AIR LOCK 1	1,42 mmH ₂ O
CLEAN ROOM – AIR LOCK 2	1,52 mmH ₂ O

Final conclusions

On the base of the results gained the Clean Room and the controlled areas of the productive plant should be considered VALIDATED in conditions "OPERATIONAL "

Definitions:

- Alert level: level of particles contamination that requires particular attention at the negative trend of the results than requires preventive action. Alert level is usually fixed at 80 % of the intervention level.
- Action level: level of particles contamination that requires immediate corrective action in case of the results overpasses the limits suggested by for each class.
- Project class: class of the room defined by UNI EN ISO 14644-1 on the basis of the customer specifications.
- Media found: the average number of particles detected in each locale is the value obtained mediating the number of particles larger and equal to 0.5 μ m per cubic metre of air sampled at each point. For the assessment of compliance with the level of alert ever established considering the average values obtained.
- Class project: means the class of contamination that the builder of the Clean Room has agreed with the developer.
- Class found: means the class of contamination actually found during the measurement.

⇒ The present test report refers only to the tested samples.

Annex 01

PLANT OF SAMPLING POINTS AIRBORNE PARTICLE CONTROL, MICROBIAL CONTROL (AIRBORNE and SURFACE) and SMOKE TEST

