

## TECHNICAL SHEET NR. 2015/ 15002410

### MAIN DATA / DATI PRINCIPALI

**Internal job N°/ODL N°:** T15L16800

**Type / Tipo:** BIO SAFETY C.S. / CABINET CLASS 2

**Code / Codice:** TSX150025 9TECH481PM

**Model / Modello:** Tech-48

**Serial number / Numero di serie:** 15002410

**Manufacturing year / Anno di fabbricazione:** 2015

**Software version / versione programma:** 1.1

**Cleanliness class ISO4 - Classe di contaminazione ISO4**

**Document code/Codice documento:** N-00000695-0-07

### TECHNICAL DATA / DATI TECNICI:

**Power supply / Alimentazione:** 230 V 50 Hz

**Electrical diagram/Schema elettrico:** 2-00027594-0

**Fan / Ventilatore:** EBM - R3G310-RO38-A1 - DC 230V 50/60 Hz

**Pre filters / Prefiltri:** SagiCofim Type PFO/S 250x500x48 Eff. G4 S.N.: B14-02500 O14-01129

**LAF Hepa Filter / Filtro Hepa LAF:** SagiCofim AB9TLV 610x1219x68 Eff. H14 S.N.: 1150006258

**Exh. Hepa Filter / Filtro Hepa Esp.:** SagiCofim MABSP375 915x457x90 Eff. H14 S.N.: 1140019567

**Touchscreen:** TEMA 134397 S.N.: 1509253160021

**Electronic board IO-BASE-OPZ / Scheda elettronica:** S.N.: 1446247090007

**Electronic board IO-EXP / Scheda elettronica:** S.N.: 1509254160039

### Tests requirements / Specifiche di collaudo:

PID	PG	IG	DG
	25	250	0

**Date / Data:** 03/08/2015 **Signature / Firma:** \_\_\_\_\_

IT	Dichiarazione di conformità	NL	Gelijkvormigheids verklaring
EN	Declaration of conformity	DA	Overensstemmelseserklæring
DE	Konformitätserklärung	SV	Försäkran om överensstämmelse
FR	Declaration de conformité	FI	Yhdenmukaisuusvakuutus
ES	Declaración de conformidad	EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΟΣΗΣ
PT	Declaração de conformidade		

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### Tech-48

#### BioSafety Cage Changing Station/Cabinet Class 2

Code: TSX150025 9TECH481PM Serial Number: 15002410  
Type: BIO SAFETY C.S. / CABINET CLASS 2

IT sono conformi a quanto prescritto dalle seguenti direttive:  
EN are in compliance with the following directives:  
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ES esperan las prescripciones contenidas en las siguientes directivas:  
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DA er i overensstemmelse med vilkårene i følgende direktiv:  
SV ← r i överensst← mmelse med villkoren i följande direktiv:  
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CE 2006/42
CE 2004/108
CE 2006/95

IT e dalle seguenti norme:  
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DE und der folgenden Normen:  
FR et des normes ci-après:  
ES y en las siguientes normas:  
PT e das seguintes normas:  
NL en van de volgende normen:  
DA samt følgende lovkrav:  
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EL και οι ερησ κανονιοι:

EN 12100 2010	EN 12469
EN 3744	
CEI EN 61010-1	EN 13091
ISO 14644-1	EN 14644-3
CEI EN 61326-1	

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Bugugiate, 03/08/2015

*Carlo Bernardini*  
Tecniplast S.p.A.  
Ing. Carlo Bernardini  
Legal Representative

**Reference standards / Norme di riferimento**

<b>CE 2006/42</b>	<b>Directive 2006/42/EC of the European Parliament and of the Council on machinery/</b> Direttiva 2006/42/EC del Parlamento europeo e del Consiglio relativa alle macchine
<b>CE 2004/108</b>	<b>Directive 2004/108/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to electromagnetic compatibility/</b> Direttiva 2004/108/CE del Parlamento europeo e del Consiglio concernente il ravvicinamento delle legislazioni degli Stati membri relative alla compatibilità elettromagnetica
<b>CE 2006/95</b>	<b>Directive 2006/95/EC of the European Parliament and of the Council on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits/</b> Direttiva 2006/95/CE del Parlamento europeo e del Consiglio concernente il ravvicinamento delle legislazioni degli Stati membri relative al materiale elettrico destinato ad essere adoperato entro taluni limiti di tensione
<b>EN 12100-2010</b>	<b>Safety of machinery:General principles for design:Risk Assessment and Risk Reduction /</b> Sicurezza del macchinario: concetti fondamentali, principi generali di progettazione.Valutazione del rischio e riduzione del rischio.
<b>EN 1822-1</b>	<b>High efficiency air filters (Hepa and Ulpa) part 1: Classification, performance testing, marking /</b> Filtri ad alta efficienza (Hepa e Ulpa) parte 1: Classificazione, test prestazionali, identificazione.
<b>EN 12469</b>	<b>Biotechnology: performance criteria for microbiological safety cabins /</b> Biotecnologie: criteri di prestazione per le postazioni di sicurezza microbiologica
<b>EN 3744</b>	<b>Acoustics: Determination of sound power levels of noise sources using sound pressure, Engineering method in an essentially free field over a reflecting plane /</b> Acustica: determinazione dei livelli di potenza sonora delle sorgenti di rumore mediante pressione sonora, metodi tecnici progettuali in campo riverberante per piccole sorgenti trasportabili.
<b>EN 13091</b>	<b>Biotechnology: performance criteria for filter elements and filtration assemblies /</b> Biotecnologie: criteri di prestazione per filtri e elementi filtranti
<b>ISO 14644-1</b>	<b>Cleanrooms and associated controlled environments: Part 1: Classification of air cleanliness /</b> Camere bianche ed ambienti associati controllati: parte 1:Classificazione della pulizia dell'aria
<b>CEI EN 61010-1</b>	<b>Safety requirements for electrical equipment for measurement, control and laboratory use Part 1: general requirements /</b> Prescrizioni di sicurezza per apparecchi elettrici di misura, controllo e per utilizzo in laboratorio. Parte 1 : prescrizioni generali
<b>CEI EN 61326-1</b>	<b>Electrical equipment for measurement, control and laboratory use EMC requirements /</b> Apparecchi elettrici di misura, controllo e laboratorio prescrizioni di compatibilità elettromagnetica
<b>EN 14644-3</b>	<b>Cleanrooms and associated controlled environments Part 3: Test methods /</b> Camere bianche ed ambienti associati controllati Parte 3: Metodi di prova

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**Electrical performance test report**

**Used instruments / Strumenti Utilizzati:**

See "Used instruments" section for reference

**Reference standards / Norme di Riferimento:**

CEI EN 61010-1

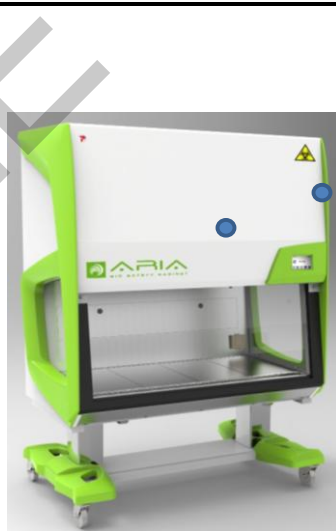
**Visual check**

OBJECT	Passed
Outlook	Y
Components	Y
Wiring	Y

**Instrumental check**

Function	Parameter	Value	Timer	Passed
Continuity 6V/10-25ac	Max resistance value	≤ 0,2 ohm	10 s	Y
Continuity 12V/>10A ac	Wire section	≤ 2,6 V	10 s	Y
Dielectric Voltage Withstand	Test Potential	840 Vac, 50Hz (115V)	2 s	Y
		1390 Vac, 50Hz (230V)		
Leakage current	Current limit	< 3,5 mA	10 s	Y
Current rate - Internal sockets not loaded (Indicative reading)	Current rate	≤ 5 A (230V/50Hz)	2,67 A	Y
		≤ 10 A (100V/50Hz.)		
Power rate - Internal sockets not loaded	Power rate	≤ 800 VA	614 VA	Y

**Check continuity between PE and illustrated point**



TECHNICIAN: Quici Antonio

SIGNATURE: \_\_\_\_\_

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## HEPA FILTER INSTALLATION & LEAK TEST (D.O.P.)

Used instruments / Strumenti Utilizzati:

See "Used instruments" section for reference

Reference standards / Norme di Riferimento

EN 12469 ; EN 1822-1 ; EN 13091 ; EN 14644-3

FILTER HEPA SUPPLY:		FILTER HEPA EXHAUST:	
SUPPLIER:	SAGI-COFIM	SUPPLIER:	SAGI-COFIM
TYPE:	AB9TLV	TYPE:	MABSP375
FILTER	H14	FILTER CLASS:	H14
SIZE (mm):	610x1219x68	SIZE (mm):	915x457x90
SERIAL NR.:	1150006258	SERIAL NR.:	1140019567
EFFICIENCY	0,995	EFFICIENCY	0,995

### RESULTS

TYPE	CRITERIA	% PENETRATION	STAND.DEV.
SUPPLY HEPA FILTER	% PENETRATION < 0.01	0,0008%	0,001
EXHAUST HEPA	% PENETRATION < 0.01	0,0001%	0,0005

### USED INSTRUMENT

Used	Instrument	Type	Serial Nr.	Description	ID Nr.
	AIRFLOW	TA5	79840	Anemometer	UT 02
	AIRFLOW	AV2	84766	Anemometer	UT 16
	AIRFLOW	AV2	109542	Anemometer	ASS 08
	TESTO	445	01726751/909	Anemometer	ASS 50
	TESTO	445	01065857/503	Anemometer	ASS 22
	TESTO	445	01581805/809	Anemometer	ASS 40
	TESTO	445	01581829/809	Anemometer	ASS 41
	TESTO	445	01715359/908	Anemometer	ASS 47
X	TESTO	445	01473736/801	Anemometer	ASS 35
	TESTO	445	01720312/909	Anemometer	ASS 51
	TESTO	445	01721977/908	Anemometer	ASS 48
	TESTO	510	38916069/802	Differential pressure	ASS 07
X	THERMO AIR 3	F.443.3.21	54554	Anemometer	ASS 25
	THERMO AIR 3	F.443.3.11	49260	Anemometer	ASS 55
	HT ITALIA	HT 4050	05072636	Fulltest	ASS 26
X	HT ITALIA	HT 4050	06012745	Fulltest	ASS 06
	HT ITALIA	HT 4060	08053103	Fulltest	ASS 46
	AHLBORN	2290-4V5	H03070656M	Luxmeter	ASS 15
X	TESTO	545	1787690	Luxmeter	ASS 52
	PACIFIC INSTR.	237B	21000085	Particel counter	ASS 01
	ATI	TDA2H	18884	Aerosol photometer	ASS 38
	ATI	TDA2H	19610	Aerosol photometer	ASS 44
	ATI	TDA2H	15980	Aerosol photometer	ASS 11
X	ATI	TDA2H	18150	Aerosol photometer	ASS 32
X	BRUEL & KJAER	2238	2201588	Noise meter	ASS 20
	BRUEL & KJAER	2238	2562790	Noise meter	ASS 03
	FLUKE	85III		Multimeter	
	CHAUVIN ARNOUX	F27	135111XFV	Power Meter	ASS 21
	TESTO		20123047/703	Thermo hygrometer	ASS 49

TECHNICIAN: Quici Antonio

SIGNATURE: \_\_\_\_\_

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**AERAILIC TESTS**

**Used instruments / Strumenti Utilizzati:** See "Used instruments" section for reference

**Reference standards / Norme di Riferimento** EN 12469

**SENSOR CALIBRATION CONDITIONS**

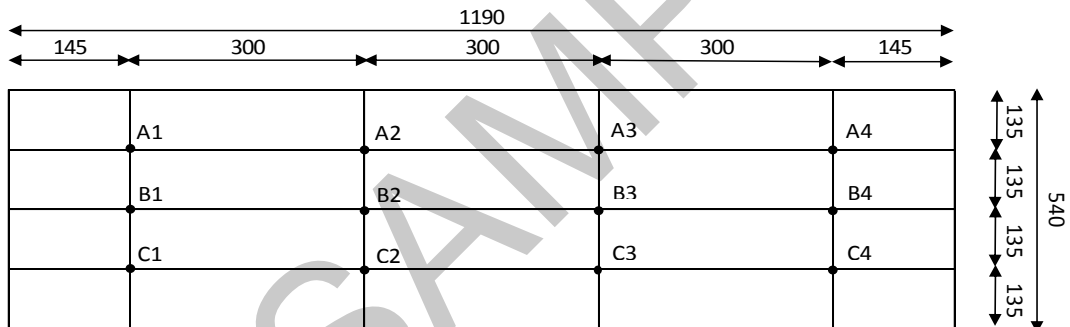
Motor supply PWM (%)  Temperature (°C)

LAF average velocity (m/s)

Exhaust average velocity (m/s)

**Bio-Safety Cabinet Class2 Configuration**

**Down flow velocity (m/s)**



Measurement plane 50mm from the window glass line

A1	0,35	A2	0,33	C3	0,33	A4	0,36
B1	0,37	B2	0,33	B3	0,35	B4	0,37
C1	0,38	C2	0,37	D3	0,37	C4	0,39

LAF Average Velocity  m/s

LAF Filter Section  m<sup>2</sup>

Max LAF Velocity  m/s

LAF Flow Rate  m<sup>3</sup>/h

Min LAF Velocity  m/s

LAF Low Alarm  m/s

Max dispersion  %

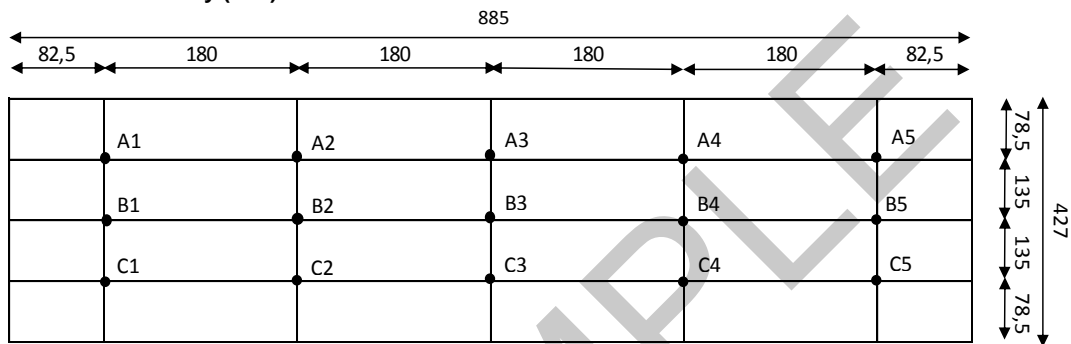
LAF High Alarm  m/s

Min dispersion  %

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## Bio-Safety Cabinet Class2 Configuration

### Exhaust airflow velocity (m/s)



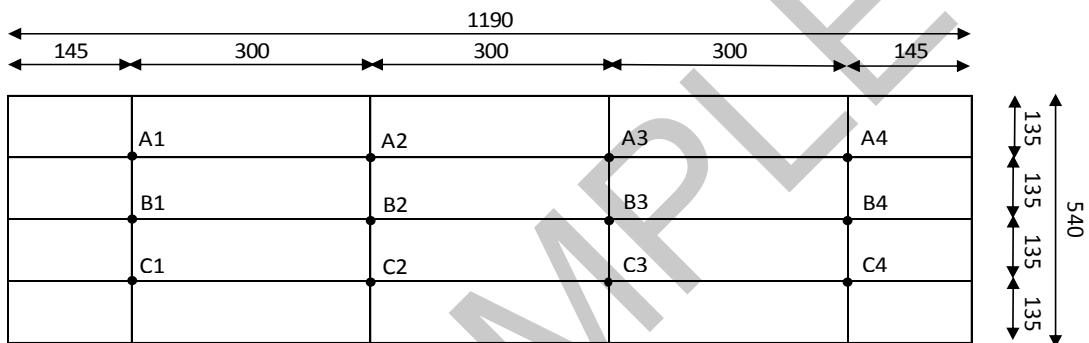
Measurement plane 100mm from the exhaust filter

A1	0,43	A2	0,43	A3	0,43	A4	0,44	A5	0,46
B1	0,45	B2	0,44	B3	0,44	B4	0,50	B5	0,52
C1	0,47	C2	0,46	C3	0,46	C4	0,49	C5	0,50

Exhaust Average Velocity	<input type="text" value="0,46"/> m/s	Exhaust Filter Section	<input type="text" value="0,3779"/> m <sup>2</sup>
Exhaust Max Velocity	<input type="text" value="0,52"/> m/s	Exhaust Flow Rate	<input type="text" value="625,80"/> m <sup>3</sup> /h
Exhaust Min Velocity	<input type="text" value="0,43"/> m/s	Front Opening Height	<input type="text" value="250"/> mm
Max dispersion	<input type="text" value="13,04"/> %	Front Opening Section	<input type="text" value="0,2946"/> m <sup>2</sup>
Min dispersion	<input type="text" value="6,52"/> %	Inward Air Velocity	<input type="text" value="0,59"/> m/s
		Inward Air Velocity Max Alarm	<input type="text" value="0,71"/> m/s
		Inward Air Velocity Min Alarm	<input type="text" value="0,47"/> m/s
Motor supply PWM (%)	<input type="text" value="64"/>		

**Changing Station Configuration**

Down flow velocity (m/s)



Measurement plane 50mm from the window glass line

A1	0,42	A2	0,37	C3	0,36	A4	0,38
B1	0,37	B2	0,34	B3	0,34	B4	0,37
C1	0,35	C2	0,34	D3	0,34	C4	0,38

LAF Average Velocity 0,36 m/s

LAF Filter Section 0,6896 m<sup>2</sup>

Max LAF Velocity 0,42 m/s

LAF Flow Rate 893,72 m<sup>3</sup>/h

Min LAF Velocity 0,34 m/s

LAF Low Alarm 0,29 m/s

Max dispersion 16,67 %

LAF High Alarm 0,43 m/s

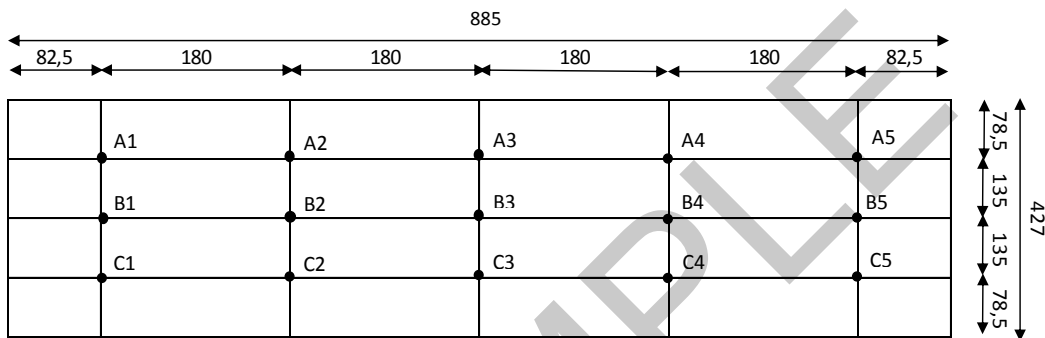
Min dispersion 5,56 %



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### Changing Station Configuration

**Exhaust airflow velocity (m/s)**



Measurement plane 100mm from the exhaust filter

A1	0,43	A2	0,42	A3	0,42	A4	0,44	A5	0,45
B1	0,43	B2	0,42	B3	0,43	B4	0,50	B5	0,5
C1	0,45	C2	0,45	C3	0,44	C4	0,46	C5	0,49

Exhaust Average Velocity	<input type="text" value="0,45"/> m/s	Exhaust Filter Section	<input type="text" value="0,3779"/> m <sup>2</sup>
Exhaust Max Velocity	<input type="text" value="0,50"/> m/s	Exhaust Flow Rate	<input type="text" value="612,20"/> m <sup>3</sup> /h
Exhaust Min Velocity	<input type="text" value="0,42"/> m/s	Front Opening Height	<input type="text" value="290"/> mm
Max dispersion	<input type="text" value="11,11"/> %	Front Opening Section	<input type="text" value="0,3417"/> m <sup>2</sup>
Min dispersion	<input type="text" value="6,67"/> %	Inward Air Velocity	<input type="text" value="0,50"/> m/s
		Inward Air Velocity Max Alarm	<input type="text" value="0,60"/> m/s
		Inward Air Velocity Min Alarm	<input type="text" value="0,40"/> m/s
Motor supply PWM (%)	<input type="text" value="64"/>		

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## NOISE MEASUREMENT

**Used instruments / Strumenti Utilizzati:** See "Used instruments" section for reference

**Reference standards / Norme di Riferimento** EN 3744 ; EN 12469

BIO SAFETY CONFIG.

Background noise (dB):  1000mm from the front opening (dB):

CHANGING STATION CONFIG.

Background noise (dB):  1000mm from the front opening (dB):

## BRIGHTNESS MEASUREMENT

**Used instruments / Strumenti Utilizzati:** See "Used instruments" section for reference

**Reference standards / Norme di Riferimento** EN 12469

Measure taken 70mm from the working plane - BIO-SAFETY CONFIGURATION

1000	1035	1035	870
1098	1140	1139	960
980	1015	1033	881

Mean brightness value (Lux):

## ALARM CHECK

Description alarm	Passed
Check Bio Safety or Changing station configuration	Y
Check open glass	Y
Stop in case of obstruction	Y
Alarm if not in standard position	Y
Low and high flow	Y
Check UV procedure	Y
Check Thouscreen in case of glass emergency	Y
Check electric socket	Y
Check lift system	Y

## SMOKE TEST

CHECK	PROCEDURE	ACCEPTANCE CRITERIA	Passed
View screen retention	Smoke shall be passed along the entire perimeter, 50mm behind the view screen, at a height of 50mm above the top access opening.	The smoke shall show smooth downward flow with no dead spots or reflux (upward flow). No smoke shall escape from the cabinet.	Y
Work opening edge retention	Smoke shall be passed along the entire perimeter, in the middle of the front opening, 50 mm outside the cabinet.	The smoke shall be refluxed out of the cabinet once drawn in nor shall smoke billow over the work surface or penetrate onto it.	Y

TECHNICIAN:                     Quici Antonio                    

SIGNATURE: \_\_\_\_\_

# PERFORMANCE CERTIFICATE

Report N° **2015/ 15002410** Date **03/08/2015**

**CONFIGURAZIONE APPARECCHIO / EQUIPMENT CONFIGURATION:** Tech48 Biosafety Cabinet CLASS 2

**NUMERO DI SERIE / SERIAL NUMBER:** **15002410**

**ANNO DI FABBRICAZIONE / MANUFACTURING YEAR:** 2015

TEST DESCRIPTION	Read Value	Internal Acceptance Criteria	Standard Acceptance Criteria	Measure Unit	Passed (Y/N)
<b>Average LAF velocity (See attachment)</b> Velocità media LAF	0,36	0,32 ÷ 0,40	0,25 ÷ 0,5	m/s	Y
<b>Max positive dispersion</b> Dispersione positiva massima	8,33%	20%	Vm ±20%	/	Y
<b>Max negative dispersion</b> Dispersione negativa massima	8,33%	20%	Vm ±20%	/	Y
<b>LAF Low Alarm</b> Valore allarme bassa velocità	0,34	≥ 0,32	0,32 m/s	m/s	Y
<b>LAF High Alarm</b> Valore allarme alta velocità	0,39	≤ 0,48	Vmax ≤ Vm+20%Vm	m/s	Y
<b>Barrier air velocity (See attachment) -</b> Velocità accesso frontale	0,59	≥ 0,52	≥0,40	m/s	Y
<b>Inflow air flow rate (See attachment) -</b> Portata di espulsione	626	≥550	≥425	m³/h	Y
<b>Smoke test</b>					Y
<b>Cleanliness class ISO4</b> Classe di contaminazione ISO4	See Attached Particles Counter Report				Y
<b>DOP Filter integrity test</b> Test integrità filtro DOP	0,001%		≤ 0,010%	/	Y
<b>Noise level</b> Livello di pressione sonora	40	≤ 50	≤55 Background	dB(A)	Y
	55,5	≤ 60	≤65	dB(A)	
<b>Light intensity at work surface</b> Intensità luminosa al piano di lavoro	1016	≥ 750	≥750	Lux	Y
<b>Electrical tests</b> Test elettrici	See Attached Test Report				Y
<b>Alarm check</b> Controllo allarmi	See Attached Test Report				Y

Signature / Firma \_\_\_\_\_

# PERFORMANCE CERTIFICATE

Report N° **2015/ 15002410** Date **03/08/2015**

**CONFIGURAZIONE APPARECCHIO / EQUIPMENT CONFIGURATION:** Tech48 Changing Station

**NUMERO DI SERIE / SERIAL NUMBER:** **15002410**

**ANNO DI FABBRICAZIONE / MANUFACTURING YEAR:** **2015**

TEST DESCRIPTION	Read Value	Internal acceptance criteria	Standard acceptance criteria	Measure Unit	Passed (Y/N)
<b>Average LAF velocity (See attachment)</b> Velocità media LAF	0,36	0,32 ÷ 0,40	0.25 ÷ 0.50	m/s	Y
<b>Max positive dispersion</b> Dispersione positiva massima	13,04%	20%	Vm ±20%	/	Y
<b>Max negative dispersion</b> Dispersione negativa massima	6,52%	20%	Vm ±20%	/	Y
<b>LAF Low Alarm</b> Valore allarme bassa velocità	0,35	≥ 0,25	0,25	m/s	Y
<b>LAF High Alarm -</b> Valore allarme alta velocità	0,42	≤ 0,48	Vmax ≤ Vm+20%Vm	m/s	Y
<b>Barrier air velocity (See attachment)</b> Velocità accesso frontale	0,50	≥ 0,48	≥ 0,40	m/s	Y
<b>Inflow rate (See attachment)</b> Portata di espulsione	612,2	≥ 580	≥ 490	m <sup>3</sup> /h	Y
<b>Smoke test</b>					Y
<b>Cleanliness class ISO4</b> Classe di contaminazione ISO4	See Attached Particles Counter Report				Y
<b>DOP Filter integrity test</b> Test integrità filtro DOP	0,001%		≤ 0,010%	/	Y
<b>Noise level</b> Livello di pressione sonora	40	≤ 50	≤ 55 Background	dB(A)	Y
	55,5	≤ 60	≤ 65	dB(A)	
<b>Electrical tests</b> Test elettrici	See Attached Test Report				Y
<b>Alarm check</b> Controllo allarmi	See Attached Test Report				Y

Signature / Firma \_\_\_\_\_

Report N° 2015/ 15002410 Date 03/08/2015

SAMPLE