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HVAC SYSTEM CLEAN ROOM ISO 5

ARS

DOCUMENT CODE: OQ.2116010.ARS

ISO 5
CLEANROOMS
COMPATIBLE

FlexiBowl[®]
by ars

CERTIFIED
ISO 5
CLASS 100
CLEANROOM

ISO14644-1:2015
standard

FlexiBowl[®]
by ars

The advertisement features a central image of two technicians in white cleanroom suits and goggles working on a piece of equipment. Below them is a FlexiBowl by ars, a cylindrical stainless steel unit with a blue mesh top, surrounded by red motion lines. The background is a dark blue gradient. The text 'ISO 5 CLEANROOMS COMPATIBLE' is overlaid on the left side of the image. At the bottom left is a circular ISO 5 Class 100 Cleanroom certification logo. At the bottom center is the text 'ISO14644-1:2015 standard'. At the bottom right is the 'FlexiBowl by ars' logo.



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FORM #11
FINAL QUALIFICATION REPORT

Form no	Verification title	Acceptance criteria	Result Compliant?		# dev.
1	Check Flow rate Premises and Hourly Changes	In each room, the total input air flow and the hourly changes are not less than those foreseen in the relevant form.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>	
2	Checking the Aerodynamic Airflow Path	the test shows no turbulence or air pockets in the area over the device.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>	27/10/2021 G.F.
3	Room pressurisation level check	The measured values are within the design specifications given in the relevant forms.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>	
4	Verification of thermo-hygrometric parameters	The measured values are within the design specifications given in the relevant forms.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>	
5	"At Rest" Environmental Contamination Class Verification	For each sampling point, the average of the concentrations of all the samples taken at each point shall be less than or equal to the class limit prescribed in the "at rest" condition; this check shall be satisfied for each particle size considered.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>	
6	Verification of "Operational" Contamination Class	For each sampling point, the average of the concentrations of all the samples taken at each point shall be less than or equal to the class limit in the "operational" condition; this check shall be satisfied for each particle size and for each product type considered.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>	

Notes:

27/10/2021 G.F.

	Company	Name	Date	Signature
Performed by:	C&P ENGINEERING	G. FIORELLI	27/10/2021	

Copy of the original document translated into English



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From the analysis of the results obtained during the various verification phases listed in this protocol and summarised in the table above, it is considered that the Operational Qualification activity of the HVAC System at the service of the Clean Room ISO 5 is to be considered:

- SUCCESSFULLY PASSED**
- PASSED WITH NON-CRITICAL NOTES** for validation activity
- NOT PASSED**

Comments:

27/07/2021 *[Signature]*

	Company	Name	Date	Signature
Performed by:	C&P ENGINEERING	G. FIORELLO	27/07/2021	<i>[Signature]</i>
Verified by:	C&P ENGINEERING	D. SOMMA	30/07/2021	<i>[Signature]</i>
Verified by:	ARS	A. PRATELLI	25/08/2021	<i>[Signature]</i>
Approved by:	ARS	S. MARTINI	25/08/2021	<i>[Signature]</i>

Operational #1 : CELL CULTURE FLASKS



Operational #2 : MICRO TUBE 2ml



Operational #3 : Sterile applicator with cotton tip



Environment qualification:

