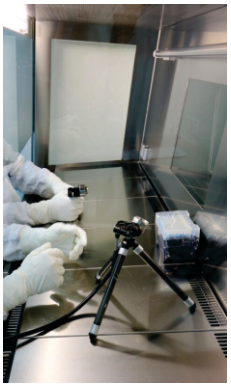
In addition of Iskra PIO's clean technology equipment production we also perform validations of:

1. Microbiological safety cabinets (class I, II, III)
2. Unidirectional flow workbenches/booths
3. Isolators
4. Clean rooms

We perform validations to confirm clean and safe working conditions. We have a qualified team and annually calibrated measuring devices for validations. After the process we prepare validation report, which is acceptable for inspection services. Following tests can be included in the validation tests:

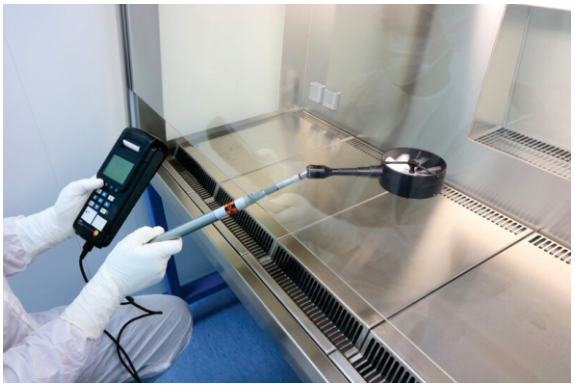
## Airborne Particle Counting

The purpose of this test is the determination of the airborne particles level in a clean room or area in accordance to ISO 14644-1 or cGMP Annex 1 standard. The instrument used to perform the test is a Laser Particle Counter.



## Filter in Place Leak Test

With this test we check the quality of the filter in accordance to ISO 14644-3 standard. The test verifies the integrity of installed filter, housing and sealing. Instruments used to perform the test are an aerosol generator and photometer/laser particle counter.

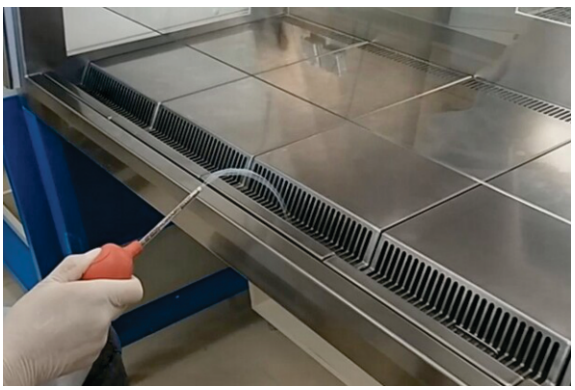


## Air Flow Velocities

The objective of this test is to check if the airflow velocities and air change rate are in accordance to the design values.

## Visual smoke test

In this test we check if the real airflows direction is in accordance to the design direction.

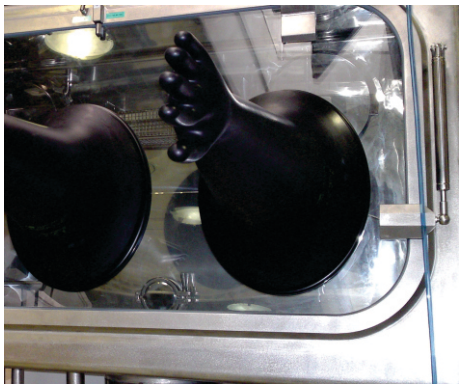


## Temperature/Humidity Measurement

This tests' goal is to check if the temperature and relative humidity in clean area are in accordance to the design values.

## Differential pressure measurement

The objective of this test is to check if the differential pressure between separate rooms or zones is in accordance to the design value.



## Tightness test

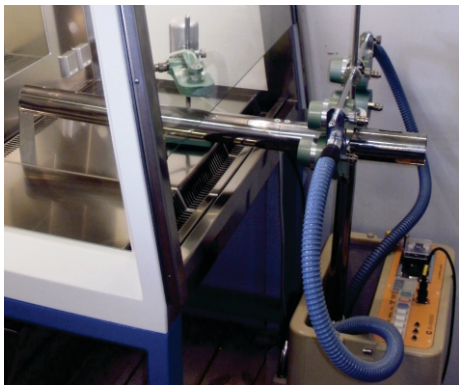
Tightness test is proving the tightness of the closed enclosure (Isolators...)

## Light Level and Noise Level

The objective of this test is to check if the light or noise level is in accordance to the design value.

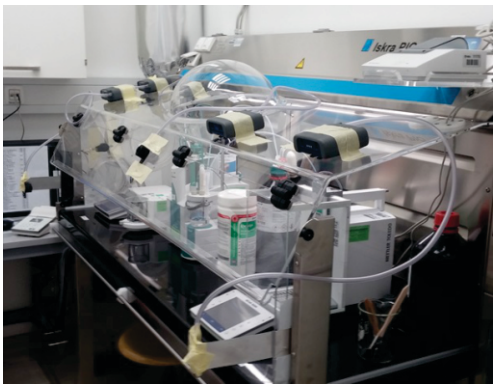
## Recovery time test

The objective of this test is to check how long does it take the room to recover from contamination.



## KI-DISCUS test

The European Standard for microbiological safety cabinets EN12469:2000 defines the KI-DISCUS test as a method for validating the operators protection capabilities of the cabinet. The KI Discus test enables determination of operator protection factors for biological safety cabinets class I and class II.



## SMEPAC test

The main purpose of the OEL (Occupational Exposure Limits) according to SMEPAC guidelines is to determine operators exposure to potentially hazardous substances while performing manufacturing process.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