

# SAS COMPLIANCE TO EN 17141

The purpose of this survey is the evaluation of the physical and biological efficiency of SAS 100 and SAS 180 air samplers.



**Physical efficiency test.** The main purpose of this test was to check if the physical performance of SAS air samplers is compliant with EN 17141 and ISO 14698 regulations; above all, EN 17141 guidelines require a limit value of d50 < 2um, meaning that the air sampler should collect over 50% of the particles with diameter size below 2um during the whole sampling.

The physical efficiency of the SAS air sampler has been determined by using a polydisperse sodium chloride aerosol and by measuring the air sampler's upstream and downstream particle concentration with the use of isokinetic probes with a particle sizer. (Image 1)

These measurements took the impact of the inner SAS fan on the particle collection fraction into account.

The final result represents the air sampler's physical efficiency, meaning the efficiency of the particles to be deposited on the collection medium. The results are shown as follows:

| Sampler | Sampling<br>head | Sampling plate type | Number of nozzles | Measured d50, µm (average ± 1 standard deviation) |
|---------|------------------|---------------------|-------------------|---|
| SAS-180 | 710-2155         | Petri dish          | 401               | 1.78 ± 0.18                                       |
| SAS-180 | 710-0878         | Petri dish          | 219               | 1.60 ± 0.02                                       |
| SAS-100 | 710-2155         | Petri dish          | 401               | 1.91 ± 0.03                                       |
| SAS-100 | 710-0878         | Petri dish          | 219               | 1.84 ± 0.02                                       |
| SAS-180 | 710-0880         | Contact plate       | 219               | 1.75 ± 0.01                                       |





FIGURE 1: All presented air sampler configurations show a result of d50 <2  $\mu$ m, so they are compliant with EN 17141 requirements.



#### **Biological efficiency test**

Biological efficiency of SAS 180 with Petri dishes, of SAS 100 with Petri dishes and SAS 180 with contact plates, has been studied using *Staphylococcus epidermidis* bacteria samples.

The bacterial aerosol, with a diameter size between 0,7 and 4,5  $\mu$ m, has been produced with a centrifugal generator device. Bacteria have been collected both from tested samplers and from a reference sample with a cut-off size of 0,65  $\mu$ m.

Concentrations expressed in CFU (units forming colonies) have been compared. All SAS air sampler's performances followed the physical collection wave. The limit size for biological efficiency is close to 2  $\mu$ m.

Therefore, tested SAS air samplers are compliant with ISO 14698 and EN 17141 regulations for all described sampling features.

All samplers of the same product family, using the same sampling heads, are then compliant to those standards because of their design and functional specifications analogy with the tested air samplers (for example double-headed air samplers).

**In conclusion,** SAS air samplers are ISO 14698 and EN 17141 compliant for all described sampling features.



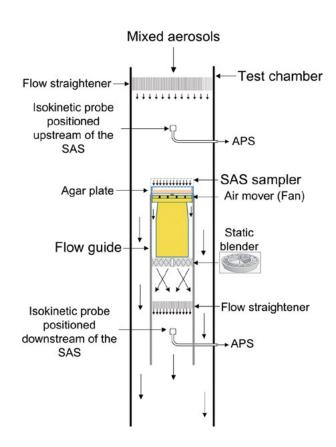
Above described assay has been performed by Gediminas "Gedi" Mainelis, Ph.D and his team.

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Mainelis is a professor of
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He has more than 20 years of experience in bioaerosol research, focused on bioaerosol sampling

technologies development and validation as well as exposure and microbiome assessment. His research includes inner air issues, including exposure and mitigation to SARS-CoV-2, producing more than 120 publications subjected to peer-reviewed and book chapters.

He received the Research Excellence Award from Rutgers University and the Lyman A. Ripperton Environmental Educator Award from A&WMA.



# Disposable SAS heads

The current EU GMP Annex 1 emphasizes the use of disposable single-use products and risk assessment devices. SAS air samplers are available both with AISI 316 stainless steel heads and with disposable single-use daily heads made up of antistatic plastic resin.

Daily heads represent a valid alternative to reduce the risks explained in the annex.

Available in 40 pcs packing size, they have a lot number, they are irradiated, double-wrapped and supplied with a sterilization certificate for traceability. They have a shelf life of five years.

SAS customers reported important time and money savings with daily heads because they don't require autoclave sterilization (as



for steel heads) and any validated autoclave. They are also essential when it is not possible to use an autoclave.



Please contact your account manager to ask for an EN 17141 and ISO 14698 compliant certificate for your SAS device or ask for an offer for a new SAS device.

| SAS Super ISO USB without aspirating head and battery charger  | Cat.No.  |
|--|----------|
| SAS Super ISO 100 USB for contact plates   | 710-2088 |
| SAS Super ISO 100 USB for Petri dishes   | 710-2090 |
| SAS Super ISO 180 USB for contact plates   | 710-2087 |
| SAS Super ISO 180 USB for Petri dishes   | 710-2089 |
| Accessories  |          |
| Battery charger with universal plug for both models (this is mandatory for the correct functioning of this instrument) | 710-2253 |
| Soft carrying case   | 710-0896 |
| Aluminium carrying case  | 710-1697 |
| SAS-Holder table and wall stainless steel  | 710-0963 |
| Adapter* to convert contact plate model to accept 90 mm Petri dishes   | 710-0882 |
| SAS stainless steel Petri head + aluminium adapter   | 110-08n  |
| SAS aluminium Petri head + adapter   | 710-0879 |
| IQ OQ validation protocols for SAS Super ISO 100 and 180 USB   | 710-0956 |
| Infrared remote control for SAS Super ISO USB  | 710-0969 |

<sup>•</sup> An aspirating head for 90 mm Petri dishes has to be used with this adopter.

| Aspirating heads            | Cat.No.  |
|-----------------------------|----------|
| For contact plates, Ø 55 mm |          |
| Stainless steel             | 710-0880 |
| Aluminium                   | 710-0892 |
| Sterile doily heads         | 710-0890 |
| For Petri dishes, Ø 90 mm   |          |
| Stainless steel             | 710-0878 |
| Aluminium                   | 710-0886 |
| Sterile doily heads         | 710-0891 |



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