

# CERTIFICATE

## of Product Conformity (QAL1)

Certificate No.: 0000028753\_02

**AMS designation:** OPSIS SM 200 for PM<sub>2.5</sub>

**Manufacturer:** OPSIS AB  
Skytteskogsvägen 16  
24402 Furulund  
Sweden

**Test Laboratory:** TÜV Rheinland Energy GmbH

This is to certify that the AMS has been tested and found to comply with:  
VDI 4202-1 (2002), VDI 4203-3 (2004), EN 14907 (2005),  
Guide to the Demonstration of Equivalence of Ambient Air Monitoring Methods (2005),  
EN 15267-1 (2009) and EN 15267-2 (2009).

Certification is awarded in respect of the conditions stated in this certificate  
(this certificate contains 9 pages).  
The present certificate replaces certificate 0000028753\_01 of 21 January 2016.



Suitability Tested  
Equivalent to  
2008/50/EC  
EN 15267  
Regular Surveillance  
  
www.tuv.com  
ID 0000028753

Publication in the German Federal Gazette  
(BAnz) of 25 August 2009

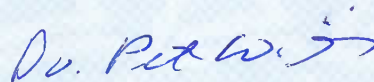
This certificate will expire on:  
25 January 2026

German Federal Environment Agency  
Dessau, 25 January 2021

TÜV Rheinland Energy GmbH  
Cologne, 24 January 2021



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Test institute accredited to EN ISO/IEC 17025 by DAkkS (German Accreditation Body).  
This accreditation is limited to the accreditation scope defined in the enclosure to certificate D-PL-11120-02-00.

<b>Test Report:</b>	936/21205849/A dated 26 March 2009
<b>Initial certification:</b>	26 January 2011
<b>Expiry date:</b>	25 January 2026
<b>Certificate:</b>	Renewal (of previous certificate 0000028753_01 dated 21 January 2016 valid until 25 January 2021)
<b>Publication:</b>	25 August 2009, no. 125, p. 2933, chapter II no. 1.1

### **Approved application**

The tested AMS is suitable for continuous ambient air monitoring of suspended particulate matter, PM<sub>2.5</sub> fraction (stationary operation). The suitability of the AMS for this application was assessed on the basis of a laboratory test and a field test performed at four different sites and/or different periods.

The AMS is approved for an ambient temperature range of +5 °C to +40 °C.

The notification of suitability of the AMS, performance testing and the uncertainty calculation have been effected on the basis of the regulations applicable at the time of testing. As changes in legal provisions are possible, any potential user should ensure that this AMS is suitable for monitoring the limit values relevant to the application.

Any potential user should ensure, in consultation with the manufacturer, that this AMS is suitable for the intended purpose.

### **Basis of the certification**

This certification is based on:

- Test report No. 936/21205849/A dated 26 March 2009 issued by TÜV Rheinland Immissionsschutz und Energiesysteme GmbH
- Suitability announced by the German Federal Environment Agency (UBA) as the relevant body
- The ongoing surveillance of the product and the manufacturing process

Publication in the German Federal Gazette: 25 August 2009, no. 125, p. 2933, chapter II no. 1.1, UBA announcement dated 03 August 2009:

**AMS designation:**

OP SIS SM 200 for PM<sub>2.5</sub>

**Manufacturer:**

OP SIS AB, Furulund, Sweden

**Field of application:**

For continuous ambient air monitoring of suspended particulate matter, PM<sub>2.5</sub> (stationary operation)

**Measuring range during performance testing:**

PM<sub>2.5</sub>: 0–200 µg/m<sup>3</sup>

**Software version:**

Version 1.04.10

**Notes:**

1. The requirements according to guide “Demonstration of Equivalence of Ambient Air Monitoring Methods” are fulfilled for the measured component PM<sub>2.5</sub>.
2. The AMS is also distributed by Aeris AB, Box 244, 244 02 Furulund, Sweden.
3. The linearity test for the radiometric measurement requires various reference foils provided by the instrument manufacturer.
4. The intake pipe must be purged with ambient air all the way up to the analyser.
5. The instrument must be calibrated on-site regularly using a gravimetric PM<sub>2.5</sub> reference method in accordance with EN 14907.

**Test Report:**

TÜV Rheinland Immissionsschutz und Energiesysteme GmbH, Cologne  
Test report No. 936/21205849/A dated 26 March 2009

Publication in the German Federal Gazette: BAnz. 26 January 2011, no. 14, p. 294, chapter IV notification 3, UBA announcement dated 10 January 2011:

**3 Notification as regards Federal Environment Agency (UBA) notice of 3 August 2009 (BAnz. p. 2929, chapter II number 2.1)**

The OPSIS SM 200 measuring system manufactured by OPSIS AB for PM<sub>2.5</sub> meets the requirements of EN 14907. Moreover, the production and quality management of the OPSIS SM 200 measuring system for PM<sub>2.5</sub> comply with the requirements of EN 15267 and of the Guide to the Demonstration of Equivalence of Ambient Air Monitoring Methods of November 2005. Furthermore, the manufacturing process and the quality management for the OPSIS SM 200 measuring system for PM<sub>2.5</sub> meets the requirements of EN 15267.

The test report on performance testing is available on the internet at [www.qal1.de](http://www.qal1.de).

Statement issued by TÜV Rheinland Energie und Umwelt GmbH dated 6 October 2010

Publication in the German Federal Gazette: BAnz AT 01.04.2014 B12, chapter VI notification 31, UBA announcement dated 27 February 2014:

**31 Notification as regards Federal Environment Agency (UBA) notices of 3 August 2009 (BAnz. p. 2929, chapter II number 2.1) and of 10 January 2011 (BAnz. p. 294, chapter IV 3<sup>rd</sup> notification)**

The latest software version of the SM 200 measuring system for PM<sub>2.5</sub> manufactured by Opsis AB is: 1.04.17

Instruments with S/N 1513 and higher are equipped with a <sup>14</sup>C light source manufactured by Eckert & Ziegler, Germany.

Statement issued by TÜV Rheinland Energie und Umwelt GmbH dated 30 September 2013

### Certified product

This certification applies to automated measurement systems conforming to the following description:

The ambient air measuring system OPSIS SM 200 is based on the measuring principle of beta-attenuation.

The PM AMS OPSIS SM 200 for PM<sub>2.5</sub> allows the sampling of suspended particulate matter on membrane filters with the option of further performance of qualitative and quantitative investigations of the sample afterwards. Furthermore, the mass of particles separated on the membrane filter during sampling is determined by means of Beta-absorption in the instrument and the concentration of suspended particulate matter in µg/m<sup>3</sup> is calculated with the flow rate.

The AMS comprises the sampling inlet, the sampling tube, the pump unit, the sampling- and measurement unit as well as the filter containers for the storage of clean and sampled filters. The filter cartridges hold 40 filters.

For sampling inlet, a PM<sub>2.5</sub> sampling inlet, acting as a pre-separator for the suspended particulate matter sampled from ambient air, is used. The instruments are operated at a constant, regulated volume flow of 38.33 l/min = 2.3 m<sup>3</sup>/h. As an alternative, the use of TSP, PM<sub>10</sub> and PM<sub>1</sub> sampling inlets is also possible.

The sampling tube connects the sampling inlet with the sampling- and measurement unit. To avoid condensation effects in the inner part of the tube when feeding the tube through the cabinet roof as well as to avoid losses of volatile components of the particulates by temperature fluctuations on the way to the sampling- and measurement unit, a feed through the roof, purged with ambient air, is in-stalled around the sampling tube (TS 200 temperature stabiliser). This ensures that the air sucked into the intake pipe remains at its original temperature until it reaches the filter.

The pump unit is connected to the sampling- and measurement unit by two hoses (inlet & outlet). The sampling- and measurement unit controls the pump and contains the mechanical system for the filter movements in the device, large parts of the pneumatic system, the measuring part and all necessary electronic parts and micro-processors for the control of the measuring system.

The measuring system is operated via a membrane keyboard at the front of the instrument. This is where all necessary parameters such as sampling time, flow throughput a. o. are set. Furthermore, features for the purpose of quality control can be activated.

### **General remarks**

This certificate is based upon the equipment tested. The manufacturer is responsible for ensuring that on-going production complies with the requirements of the EN 15267. The manufacturer is required to maintain an approved quality management system controlling the manufacturing process for the certified product. Both the product and the quality management systems shall be subject to regular surveillance.

If a product of the current production does not conform to the certified product, TÜV Rheinland Energy GmbH must be notified at the address given on page 1.

A certification mark with an ID-Number that is specific to the certified product is presented on page 1 of this certificate.

This document as well as the certification mark remains property of TÜV Rheinland Energy GmbH. Upon revocation of the publication the certificate loses its validity. After the expiration of the certificate and on request of TÜV Rheinland Energy GmbH this document shall be returned and the certificate mark must no longer be used.

The relevant version of this certificate and its expiration date are also accessible on the internet at [qal1.de](http://qal1.de).

### **Document history**

Certification of the OPSIS SM 200 measuring system is based on the documents listed below and the regular, continuous surveillance of the manufacturer's quality management system:

#### **Basic testing**

Test Report: 936/21205849/A dated 26 March 2009  
TÜV Rheinland Immissionsschutz und Energiesysteme GmbH, Cologne  
Publication: BAnz. 25 August 2009, no. 125, p. 2933, chapter II number 1.1  
UBA announcement dated 3 August 2009

#### **Initial certification according to EN 15267**

Certificate no. 0000028753: 09 February 2011  
Expiry date of the certificate: 25 January 2016  
Statement issued by TÜV Rheinland Energie und Umwelt GmbH dated 6 October 2010  
Test Report: 936/21205849/A dated 26 March 2009  
TÜV Rheinland Immissionsschutz und Energiesysteme GmbH, Cologne  
Publication: BAnz. 26 January 2011, no. 14, p. 296, chapter IV notification 3  
UBA announcement dated 10 January 2011

#### **Notifications in accordance with EN 15267**

Statement issued by TÜV Rheinland Energie und Umwelt GmbH dated 30 September 2013  
Publication: BAnz AT 01.04.2014 B12, chapter VI notification 31  
UBA announcement dated 27 February 2014  
(alternative <sup>14</sup>C light source)

**Renewal of the certificate:**

Certificate no. 0000028753\_01: 21 January 2016  
Expiry date of the certificate: 25 January 2021

**Renewal of the certificate**

Certificate no. 0000028753\_02: 25 January 2021  
Expiry date of the certificate: 25 January 2026

## Results of the equivalence test performed to demonstrate equivalence as required by the EU guide of November 2005

Performance test as reported in 936/21205849/A dated 26 March 2009

Test specimen 1 vs. Test specimen 2

Tested instruments	Location	Number of measurements	Uncertainty $u_{bs}$
SN			$\mu\text{g}/\text{m}^3$
1236 / 1237	Cologne Frankfurter Str.	90	1.019
1236 / 1237	Cologne Parking lot	69	0.965
1236 / 1237	Furulund (Summer)	56	1.007
1236 / 1237	Furulund (Winter)	76	0.768
1236 / 1237	All locations	291	0.944
Classing over reference values			
1236 / 1237	Values $\geq$ 50% ALV 1 ( $\geq 12.5 \mu\text{g}/\text{m}^3$ )	79	1.114
1236 / 1237	Values $\geq$ 50% ALV 2 ( $\geq 10 \mu\text{g}/\text{m}^3$ )	99	1.061
1236 / 1237	Values $<$ 50% ALV 1 ( $< 12.5 \mu\text{g}/\text{m}^3$ )	93	0.834
1236 / 1237	Values $<$ 50% ALV 2 ( $< 10 \mu\text{g}/\text{m}^3$ )	73	0.837



Test specimens vs. Reference

PM <sub>2.5</sub>	Limit value	Slope b	Axis intercept a	u <sub>c,s</sub> at the limit value	w <sub>CM</sub>	W <sub>CM</sub>	W <sub>CM</sub> ≤ W <sub>dqo</sub> (W <sub>dqo</sub> = 25%)
Location	µg/m <sup>3</sup>	(µg/m <sup>3</sup> )/(µg/m <sup>3</sup> )	µg/m <sup>3</sup>	µg/m <sup>3</sup>	%	%	
Cologne Frankfurter Str.	25	0.99	0.47	1.62	6.46	12.92	yes
	20	0.99	0.47	1.62	8.11	16.23	yes
Cologne Parking lot	25	1.01	1.49	2.38	9.52	19.04	yes
	20	1.01	1.49	2.34	11.72	23.45	yes
Furulund (Summer)	25	1.00	2.06	2.50	9.98	19.97	yes
	20	1.00	2.06	2.49	12.47	24.94	yes
Furulund (Winter)	25	1.09	0.46	2.93	11.74	23.48	yes
	20	1.09	0.46	2.49	12.44	24.88	yes
All locations	25	1.00	1.41	2.06	8.23	16.45	yes
	20	1.00	1.41	2.07	10.35	20.70	yes
Values ≥ 50% ALV 1 (≥ 12.5 µg/m <sup>3</sup> )	25	0.99	1.54	2.16	8.65	17.29	yes
Values ≥ 50% ALV 2 (≥ 10 µg/m <sup>3</sup> )	20	1.00	1.25	2.09	10.47	20.95	yes