

# CERTIFICATE

## of Product Conformity (QAL1)

Certificate No.: 0000028753\_03

**Certified AMS:** SM 200 for PM<sub>2,5</sub>

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

**Test Institute:** TÜV Rheinland Energy GmbH

This is to certify that the AMS has been tested  
and found to comply with the standards  
VDI 4202-1 (2002), VDI 4203-3 (2004), EN 16450 (2017), EN 14907 (2005),  
Guide for Demonstration of Equivalence of Ambient Air Monitoring Methods (2010),  
EN 15267-1 (2009) and EN 15267-2 (2009).

Certification is awarded in respect of the conditions stated in this certificate  
(this certificate contains 8 pages).  
The present certificate replaces certificate 0000028753\_02 dated 25 January 2021.



Suitability Tested  
Complying with  
2008/50/EC  
EN 15267  
Regular  
Surveillance  
[www.tuv.com](http://www.tuv.com)  
ID 0000028753

Publication in the German Federal Gazette  
(BAnz) of 11 April 2022

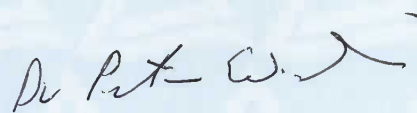
German Environment Agency  
Dessau, 31 May 2022



Dr. Marcel Langner  
Head of Section II 4.1

This certificate will expire on:  
11 April 2027

TÜV Rheinland Energy GmbH  
Cologne, 30 May 2022



ppa. Dr. Peter Wilbring

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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 the certificate D-PL-11120-02-00.

<b>Test report:</b>	936/21205849/A dated 26 March 2009 and addendum 936/21251664/A dated 10 September 2021
<b>Initial certification:</b>	09 February 2011
<b>Expiry date:</b>	11 April 2027
<b>Publication:</b>	BAnz AT 11.04.2022 B10, Chap. VI Notification 19

### **Approved application**

The tested AMS is suitable for continuous ambient air monitoring of the PM<sub>2,5</sub> fraction (stationary operation).

The suitability of the AMS for these applications was assessed based on a laboratory test and a field test at four different locations and over different time periods.

The AMS is approved for an ambient temperature range of +5° 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 measured values relevant to the application.

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

### **Basis of the certification**

This certification is based on:

- Test report 936/21205849/A dated 26 March 2009 issued by TÜV Rheinland Immissionsschutz und Energiesysteme GmbH and
- Addendum 936/21251664/A dated 10 September 2021 by TÜV Rheinland Energy GmbH
- Suitability announced by the German Environment Agency (UBA) as the relevant body
- The ongoing surveillance of the product and the manufacturing process

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

**AMS designation:**

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

**Manufacturer:**

Opsis AB

**Field of application:**

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

**Measuring ranges during performance testing:**

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

**Software version:**

Version 1.04.10

**Notes:**

1. The measuring system complies with the requirements of the guide to “Demonstration of Equivalence of Ambient Air Monitoring Methods” for the component PM<sub>2.5</sub>.
2. The measuring system is also distributed by the company Aeris AB, Box 244, 244 02 Furulund, Sweden.
3. The linearity check of the radiometric measurement requires the use of various reference foils provided by the system 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 the gravimetric PM<sub>2.5</sub> reference method in accordance with EN 14907.

**Test report:**

TÜV Rheinland Immissionsschutz und Energiesysteme GmbH, Cologne  
Report no.: 936/21205849/A dated 26 March 2009



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

**3 Notification as regards Federal Environment Agency (UBA) notice of 03 August 2009 (BAnz. p. 2929, chapter II, number 2.1)**

The OPSIS SM 200 for PM<sub>2.5</sub> measuring system manufactured by OPSIS AB fulfils the requirements of EN 14907 and the Guide for Demonstration of Equivalence of Ambient Air Monitoring Methods, version November 2005. Furthermore, the manufacturing process and the quality management for the OPSIS SM 200 measuring system for PM<sub>2.5</sub> meet 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 06 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 03 August 2009 (BAnz. p. 2929, chapter II, number 2.1) and of 10 January 2011 (BAnz. p. 294, chapter IV 3rd notification)**

The current software version for 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 beta source manufactured by Eckert & Ziegler.

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

Publication in the German Federal Gazette: BAnz AT 11.04.2022 B10, chapter VI notification 19, Announcement by UBA dated 09 March 2022:

**19 Notification as regards Federal Environment Agency (UBA) notices of 3 August 2009 (BAnz. p. 2933, chapter II number 1.1) and of 27 February 2014 (BAnz AT 01.04.2014 B12, chapter VI notification 31)**

The OPSIS SM 200 measuring device for PM<sub>2.5</sub> of the company OPSIS AB meets the requirements of EN 16450 (July 2017 edition). An addendum to the test report with the report number 936/21251664/A can be viewed on the Internet at [www.qal1.de](http://www.qal1.de).

The current software version is: 1.04 R:20

Statement issued by TÜV Rheinland Energy GmbH dated 10 September 2021

## Certified product

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

The OPSIS SM 200 ambient air monitor for suspended matter is based on the measuring principle of beta attenuation.

The OPSIS SM 200 PM<sub>2,5</sub> enables the sampling of suspended particulate matter on membrane filters, with the option of performing further qualitative and quantitative tests of the collected sample afterwards. In addition, the particulate mass deposited on the membrane filter during sampling is determined by beta absorption in the instrument, and the volume passed through is used to calculate the suspended particulate concentration in µg/m<sup>3</sup>.

The AMS consists of the sampling head and the suction pipe, the pump unit, the sampling and measuring unit, and the filter containers for storing the used and unused filters. The filter containers provide space for 40 filters.

A PM<sub>2,5</sub> sample inlet, which acts as a pre-separator for the airborne particulate matter drawn in from the outside air, is used as the sampling head. The units are operated with a constant, regulated volume flow of 38.33 l/min = 2.3 m<sup>3</sup>/h. Alternatively, it is also possible to use TSP, PM<sub>10</sub> and PM1 sampling inlets.

The intake tube forms the connection between the sampling head and the sampling and measuring unit. To prevent condensation inside the tube when the intake tube passes through the measuring container roof, and to prevent losses of volatile dust components due to temperature fluctuations on the way to the sampling and measuring unit, tubing flushed with outside air is installed around the intake tube through the roof (TS 200 temperature stabilizer). The ambient air circulating in the outer tube ensures that the sampled air in the inner tube maintains its original temperature all the way to the filter.

The pump unit is connected to the sampling and measuring unit via two hoses (inlet and outlet). The sampling and measuring unit controls the pump and also includes the mechanical system for moving the filters in the instrument, large parts of the pneumatic system, the measuring system and all the necessary electronic equipment and microprocessors for controlling and monitoring the AMS.

The measuring system is operated via a keypad on the front of the device. There, all necessary parameters, e.g. sampling time, enforced volume, etc., are set. Quality control functions can also be activated.

## General notes

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 manufacture of 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 certification mark may be applied to the product or used in advertising materials for the certified product.



This document and the certification mark remains property of TÜV Rheinland Energy GmbH. With revocation of the publication the certificate loses its validity. After the expiration of the certificate and on requests of the TÜV Rheinland Energy GmbH this document shall be returned and the certificate mark must not be employed anymore.

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

### History of documents

Certification of SM 200 PM<sub>2,5</sub> is based on the documents listed below and the regular, continuous monitoring of the Quality Management System of the manufacturer:

### Basic test

Test report 936/21205849/A dated 26 March 2009  
TÜV Rheinland Immissionsschutz und Energiesysteme GmbH  
Publication BAnz. 25 August 2009, No. 125, p. 2929, chapter II number 1.1  
UBA announcement dated 3 August 2009

### Initial certification according to EN 15267

Certificate No. 0000028753\_00: 09 February 2011  
Expiry date of the certificate: 24 August 2014  
Statement issued by TÜV Rheinland Immissionsschutz und Energiesysteme GmbH dated 6 October 2010  
Test report 936/21205849/A dated 26 March 2009  
Publication BAnz. 26 January 2011, No. 14, p. 294, chapter IV number 3  
UBA announcement dated 10 January 2011

### Notifications

Statement issued by TÜV Rheinland Energy GmbH dated 4 September 2013  
Publication BAnz AT 01.04.2014 B12, chapter VI notification 31  
UBA announcement dated 27 February 2014  
(Soft- and hardware changes)

### Renewal of certificate

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

### Renewal of certificate

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

### Certificate based on a notification

Certificate No. 0000028753\_03: 31 May 2022  
Expiry date of the certificate: 11 April 2027  
Statement issued by TÜV Rheinland Energy GmbH dated 10 September 2021  
Test report 936/21251664/A dated 10 September 2021  
Publication BAnz AT 11.04.2022 B10, chapter VI number 19  
UBA announcement dated 9 March 2022  
(Comply with EN 16450 (2017), an addendum is added to the test report.)

Comparison candidate with reference according to Standard EN 16450:2017				
Candidate	SM 200	SN	SN 1236 / SN 1237	
Status of measured values	Offset corrected	Limit value	30	$\mu\text{g}/\text{m}^3$
		Allowed uncertainty	25	%
All comparisons				
Uncertainty between Reference	0.51			$\mu\text{g}/\text{m}^3$
Uncertainty between Candidates	1.13			$\mu\text{g}/\text{m}^3$
	<b>SN 1236 / SN 1237</b>			
Number of data pairs	175			
Slope b	0.998		not significant	
Uncertainty of b	0.015			
Ordinate intercept a	0.000		not significant	
Uncertainty of a	0.237			
Expanded meas. uncertainty $W_{CM}$	11.37		%	
All comparisons, $\geq 18 \mu\text{g}/\text{m}^3$				
Uncertainty between Reference	0.50			$\mu\text{g}/\text{m}^3$
Uncertainty between Candidates	1.34			$\mu\text{g}/\text{m}^3$
	<b>SN 1236 / SN 1237</b>			
Number of data pairs	50			
Slope b	1.044			
Uncertainty of b	0.049			
Ordinate intercept a	-1.464			
Uncertainty of a	1.243			
Expanded meas. uncertainty $W_{CM}$	12.38		%	
All comparisons, $< 18 \mu\text{g}/\text{m}^3$				
Uncertainty between Reference	0.52			$\mu\text{g}/\text{m}^3$
Uncertainty between Candidates	1.05			$\mu\text{g}/\text{m}^3$
	<b>SN 1236 / SN 1237</b>			
Number of data pairs	125			
Slope b	1.065			
Uncertainty of b	0.032			
Ordinate intercept a	-0.467			
Uncertainty of a	0.320			
Expanded meas. uncertainty $W_{CM}$	14.89		%	

Comparison candidate with reference according to Standard EN 16450:2017				
Candidate	SM 200	SN	SN 1236 / SN 1237	
Status of measured values	Offset corrected	Limit value	30	$\mu\text{g}/\text{m}^3$
		Allowed uncertainty	25	%
<b>Cologne, Frankf. Str.</b>				
Uncertainty between Reference	0.39	$\mu\text{g}/\text{m}^3$		
Uncertainty between Candidates	1.35	$\mu\text{g}/\text{m}^3$		
	SN 1236		SN 1237	
Number of data pairs	53		53	
Slope b	0.998		1.015	
Uncertainty of b	0.036		0.023	
Ordinate intercept a	-1.534		-1.037	
Uncertainty of a	0.676		0.443	
Expanded meas. uncertainty $W_{CM}$	18.86	%	10.86	%
<b>Cologne, Parking lot</b>				
Uncertainty between Reference	0.50	$\mu\text{g}/\text{m}^3$		
Uncertainty between Candidates	0.96	$\mu\text{g}/\text{m}^3$		
	SN 1236		SN 1237	
Number of data pairs	41		41	
Slope b	0.993		1.034	
Uncertainty of b	0.044		0.034	
Ordinate intercept a	0.036		0.182	
Uncertainty of a	0.829		0.645	
Expanded meas. uncertainty $W_{CM}$	13.44	%	13.08	%
<b>Furulund, Summer</b>				
Uncertainty between Reference	0.61	$\mu\text{g}/\text{m}^3$		
Uncertainty between Candidates	1.29	$\mu\text{g}/\text{m}^3$		
	SN 1236		SN 1237	
Number of data pairs	40		40	
Slope b	1.035		0.998	
Uncertainty of b	0.071		0.051	
Ordinate intercept a	0.608		0.678	
Uncertainty of a	0.509		0.364	
Expanded meas. uncertainty $W_{CM}$	17.12	%	9.94	%
<b>Furulund, Winter</b>				
Uncertainty between Reference	0.55	$\mu\text{g}/\text{m}^3$		
Uncertainty between Candidates	0.76	$\mu\text{g}/\text{m}^3$		
	SN 1236		SN 1237	
Number of data pairs	41		41	
Slope b	1.095		1.094	
Uncertainty of b	0.018		0.022	
Ordinate intercept a	-0.533		-1.217	
Uncertainty of a	0.279		0.332	
Expanded meas. uncertainty $W_{CM}$	16.71	%	13.07	%
<b>All comparisons, <math>\geq 18 \mu\text{g}/\text{m}^3</math></b>				
Uncertainty between Reference	0.50	$\mu\text{g}/\text{m}^3$		
Uncertainty between Candidates	1.34	$\mu\text{g}/\text{m}^3$		
	SN 1236		SN 1237	
Number of data pairs	50		50	
Slope b	1.053		1.063	
Uncertainty of b	0.063		0.043	
Ordinate intercept a	-2.082		-1.513	
Uncertainty of a	1.602		1.09	
Expanded meas. uncertainty $W_{CM}$	16.49	%	11.02	%
<b>All comparisons, <math>&lt; 18 \mu\text{g}/\text{m}^3</math></b>				
Uncertainty between Reference	0.52	$\mu\text{g}/\text{m}^3$		
Uncertainty between Candidates	1.05	$\mu\text{g}/\text{m}^3$		
	SN 1236		SN 1237	
Number of data pairs	125		125	
Slope b	1.089		1.067	
Uncertainty of b	0.039		0.030	
Ordinate intercept a	-0.693		-0.478	
Uncertainty of a	0.391		0.302	
Expanded meas. uncertainty $W_{CM}$	19.22	%	14.64	%
<b>All comparisons</b>				
Uncertainty between Reference	0.51	$\mu\text{g}/\text{m}^3$		
Uncertainty between Candidates	1.13	$\mu\text{g}/\text{m}^3$		
	SN 1236		SN 1237	
Number of data pairs	175		175	
Slope b	0.986	not significant	1.018	not significant
Uncertainty of b	0.018		0.014	
Ordinate intercept a	0.036	not significant	-0.142	not significant
Uncertainty of a	0.296		0.219	
Expanded meas. uncertainty $W_{CM}$	14.49	%	10.77	%