Umwelt Bundesamt

TÜVRheinland®
Precisely Right.

CERTIFICATE

of Product Conformity (QAL1)

Certificate No.: 0000028753_01

Certified AMS:	OPSIS SM 200 for $PM_{2.5}$
Manufacturer:	OPSIS AB Box 244 244 02 Furulund Sweden
Test Institute:	TÜV Rheinland Energie und Umwelt GmbH

This is to certify that the AMS has been tested and certified according to the standards

VDI 4202-1 (2002), VDI 4203-3 (2004), EN 14907 (2005), Guide to 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 8 page).

TÜVRheinland®
CERTIFIED

Suitability Tested
Complying with
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 2021

German Federal Environment Agency
Dessau, 21 January 2016

i. A. Dr. Marcel Langner

TÜV Rheinland Energie und Umwelt GmbH
Cologne, 20 January 2016

ppa. Dr. Peter Wilbring

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TÜV Rheinland Energie und Umwelt GmbH
Am Grauen Stein
51105 Cologne

Test institute accredited to EN ISO/IEC 17025:2005 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.

10/221 2.08

Test report:	936/21205849/A of 26 March 2009
Initial certification:	26 January 2011
Certificate:	renewal (previous certificate 0000028753 of 09 February 2011 valid until 25 January 2016)
Date of expiry:	25 January 2021
Publication:	BAnz. 25 August 2009, No. 125, page 2933, Chapter II No. 1.1

Approved application
The certified AMS is approved for permanent monitoring of suspended particulate matter $PM_{2.5}$ in ambient air (stationary operation). The suitability of the product for this application was assessed on the basis of a laboratory test and a field test at four different test sites respectively time periods

The AMS is approved for the 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 valid at the time of performance testing. As changes in legal regulations are possible, any potential user should ensure that this AMS is suitable for monitoring the limit value relevant to the application.

Any potential user should ensure, in consultation with the manufacturer, that this AMS is suitable for ambient air applications at which it will be installed.

Basis of the certification
This certification is based on:

- test report 936/21205849/A of 26 March 2009 of TÜV Rheinland Energie und Umwelt GmbH
- suitability announced by the German Federal Environment Agency (UBA) as the relevant body
- the on-going 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, Announcement by UBA from 3 August 2009:

AMS name:
OPSIS SM 200 for $PM_{2.5}$

Manufacturer:
OPSIS AB, Furulund, Sweden

Approval:
For permanent monitoring of suspended particulate matter $PM_{2.5}$ in ambient air (stationary operation).

Measuring range during the suitability test:
$PM_{2,5}$: 0 – 200 µg/m^3

Software version:
Version 1.04.10

Remarks:
1. The requirements according to guide “Demonstration of Equivalence of Ambient Air Monitoring Methods” are fulfilled for the measured component $PM_{2.5}$.
2. The AMS is also distributed by the company Aeris AB, Box 244, 244 02 Furulund, Sweden.
3. The linearity check of the radiometric measurement requires different reference foils of the instrument manufacturer.
4. The sampling tube has to be purged with ambient air up to the analyser.
5. The measuring system is to be calibrated on site in regular intervals with the gravimetric $PM_{2.5}$ reference method according to EN 14907.

Test report:
TÜV Rheinland Immissionsschutz und Energiesysteme GmbH, Cologne
Report-No.: 936/21205849/A of 26 March 2009

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

3 Notification on the announcement of the Federal Environment Agency of 3 August 2009 (BAnz. p 2929, Chapter II No. 1.1)

The OPSIS SM 200 measuring system by OPSIS AB for component $PM_{2.5}$ fulfils the requirements of EN 14907. Moreover, the production and quality management of the OPSIS SM 200 measuring system for component $PM_{2.5}$ complies with the requirements of EN 15267 and of the Guideline „Demonstration of Equivalence of Ambient Air Monitoring Methods“, version of November 2005.
The report of the suitability test is available on the internet at www.qal1.de.

Statement of TÜV Rheinland Energie und Umwelt GmbH of 6 October 2010

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

31 Notification on the announcement of the Federal Environment Agency of 3 August 2009 (BAnz. p 2929, Chapter II No. 2.1) and of 10 January 2011 (BAnz. p 294, Chapter IV 3th notification)

The current software version for the SM 200 measuring system with $PM_{2,5}$ pre-separator by Opsis AB is: 1.04.17

As of serial number SN 1513, the measuring system will be equipped with an alternative ^{14}C radiation source by Eckert & Ziegler, Germany.

Statement of TÜV Rheinland Energie und Umwelt GmbH of 30 September 2013

Certified product
This certificate applies to automated measurement systems confirming to the following description:

The ambient air measuring system OPSIS SM 200 for $PM_{2.5}$ is based on the measuring principle of beta-attenuation.

The PM AMS OPSIS SM 200 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 device and the concentration of suspended particulate matter in µg/m³ is calculated with the sampled volume.

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 container has capacity for 40 filters.

For sampling inlet, a $PM_{2.5}$-sampling inlet, acting as a pre-separator for the suspended particulate matter sampled from ambient air, is used. The devices are operated with a constant, regulated volume flow of 38.33 l/min = 2.3 m³/h. As an alternate, the use of TSP, PM_{10} and PM_1-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 installed around the sampling tube (temperature stabilizer TS 200). This secures, that the sampled air in the tube keeps its initial temperature up to 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 device.

The operation of the device is done via a foil keypad at the front panel of the device. All required parameters, e.g. sampling time, sampled volume etc are set here. Furthermore several functions for quality control can 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 Energie und Umwelt 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 can be applied to the product or used in publicity material for the certified product is presented on page 1 of this certificate.

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

The relevant version of this certificate and the validity is also accessible on the internet: **qal1.de**.

Certification of OPSIS SM 200 with $PM_{2.5}$ pre-separator for suspended particulate matter $PM_{2.5}$ is based on the documents listed below and the regular, continuous monitoring of the Quality Management System of the manufacturer:

First suitability test:

Test report: 936/21205849/A of 26 March 2009,
TÜV Rheinland Immissionsschutz und Energiesysteme GmbH, Cologne,

Publication: BAnz. 25 August 2009, No. 125, p. 2933, Chapter II No. 1.1,
Announcement by UBA from 3 August 2009

Initial certification according to EN 15267:

Certificate No. 0000028753: 9 February 2011

Validity of the certificate: 25 January 2016
Statement of TÜV Rheinland Energie und Umwelt GmbH of 6 October 2010,
Test report: 936/21205849/A of 26 March 2009,
TÜV Rheinland Immissionsschutz und Energiesysteme GmbH, Cologne,
Publication: BAnz. 26. January 2011, No. 14, p. 296, Chapter IV, notification 3,
Announcement by UBA from 10 January 2011

Notifications

Statement of TÜV Rheinland Energie und Umwelt GmbH of 30 September 2013,
Publication: BAnz AT 01.04.2013 B12, chapter VI, notification 31,
Announcement by UBA from 27 February 2014 (alternative ^{14}C radiation source)

Renewal of the certificate:

Certificate No : 0000028753_01: 21 January 2016

Validity of the certificate: 25 January 2021

Results of the equivalence test for the demonstration of equivalence according to the EC-Guide of November 2005

Type-approval test from 936/21205849/A of 2009-03-26

Candidate 1 vs. Candidate 2

Candidates	Test site	No. of values	Uncertainty u_{bs}
SN			µg/m³
1236 / 1237	Köln, Frankfurter Str.	90	1.019
1236 / 1237	Köln, Parking lot	69	0.965
1236 / 1237	Furulund (Summer)	56	1.007
1236 / 1237	Furulund (Winter)	76	0.768
1236 / 1237	All test sites	291	0.944
Classification via reference values			
1236 / 1237	Values ≥ 50 % ALV 1 (≥ 12.5 µg/m³)	79	1.114
1236 / 1237	Values ≥ 50 % ALV 2 (≥ 10 µg/m³)	99	1.061
1236 / 1237	Values < 50 % ALV 1 (< 12.5 µg/m³)	93	0.834
1236 / 1237	Values < 50 % ALV 2 (< 10 µg/m³)	73	0.837

Candidate vs. Reference

PM2.5 **Test site**	**Limit value ALV** µg/m³	**Slope b** (µg/m³)/(µg/m³)	**Intercept a** µg/m³	**u_{c_s} at limit value** µg/m³	**w_{CM}** %	**W_{CM}** %	**$W_{CM} \leq W_{dqo}$** (W_{dqo} = 25 %)
Köln, 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
Köln, 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
Alle test sites	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/m³)	25	0.99	1.54	2.16	8.65	17.29	yes
Values ≥ 50 % ALV 2 (≥ 10 µg/m³)	20	1.00	1.25	2.09	10.47	20.95	yes