

CERTIFICATE

of Product Conformity (QAL1)

Certificate No. : 0000027201_01

Certified AMS: OPSIS SM 200 with PM₁₀-pre-separator

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 12341 (1998),
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).



Suitability Tested
Complying with
2008/50/EC
EN 15267
Regular
Surveillance

www.tuv.com
ID 0000027201

Publication in the German Federal Gazette
(BAnz.) of 29 October 2005

German Federal Environment Agency
Dessau, 21 January 2016


i. A. Dr. Marcel Langner

This certificate will expire on:
25 January 2021

TÜV Rheinland Energie und Umwelt GmbH
Cologne, 20 January 2016


ppa. Dr. Peter Wilbring

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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.

Certificate:
0000027201_01 / 21 January 2016

Test report: 936/21201592/A of 5 July 2005
Initial certification: 26 January 2011
Certificate: renewal (previous certificate 0000027201 of 09 February 2011
valid until 25 January 2016)
Date of expiry: 25 January 2021
Publication: BAnz. 29 October 2005, No. 206, p. 15702, Chapter IV No. 1.1

Approved application

The AMS is approved for permanent monitoring of suspended particulate matter PM₁₀ 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 five 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 936/21201592/A of 5 July 2005 of TÜV Immissionsschutz und Energiesysteme 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. 29 October 2005, No. 206, p. 15702, Chapter IV
No. 1.1: Announcement by UBA from 25 July 2005:

AMS name:

OPSIS SM 200 with PM₁₀- pre-separator

Manufacturer:

OPSIS AB, Furulund, Sweden

Approval:

For permanent monitoring of suspended particulate matter PM₁₀ in ambient air (stationary operation).

Measuring ranges during the suitability test:

0 – 200 µg/m³

Software:

Version 1.03 (OPSIS SM 200 (New))

Remarks:

1. Supplementary test on the publication of suitability (announcement of 22 April 2003, BAnz. p. 10742)
2. The two versions of the AMS are safely distinguished by the serial number:
SN < 1000 = OPSIS SM 200, old version TÜV-Report-No.: 936/801013A
SN > 1000 = OPSIS SM 200, new version TÜV-Report-No.: 936/21201592/A
3. The AMS is also distributed under the name Aeris AB, Box 244, 244 02 Furulund, Sweden.
4. The AMS shall be operated in a lockable measuring cabinet.
5. The linearity check of the radiometric measurement requires different reference foils of the instrument manufacturer.
6. The sampling tube shall be purged with ambient air up to the analyser (option C).
7. The measuring equipment has to be calibrated with the gravimetric PM₁₀ reference procedure by EN 12341.

Testing Institute:

TÜV Immissionsschutz und Energiesysteme GmbH, Cologne
TÜV Rheinland Group

Test report:

No.: 936/21201592/A of 5 July 2005

Publication in the German Federal Gazette: BAnz. 26 January 2011, No. 14, p. 296, chapter IV
notification 4: Announcement by UBA from 10 January 2011:

4 Notification on the announcement of the Federal Environment Agency of 25 July 2005 (BAnz. p. 15702, chapter IV No. 1.1) and of 3 August 2009 (BAnz. p. 2929, chapter III, Notification 13)

The OPSIS SM 200 measuring system by OPSIS AB for component PM₁₀ fulfils the requirements of EN 12341. Moreover, the production and quality management of the OPSIS SM 200 measuring system for component PM₁₀ complies with the requirements of EN 15267.

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 30,
Announcement by UBA from 27 February 2014:

30 Notification on the announcements of the Federal Environment Agency of 25 July 2005 (BAnz. p. 15700, Chapter IV Number 1.1) and of 10 January 2011 (BAnz. p. 294, chapter IV 4th notification)

The current software version for the SM 200 measuring system with PM₁₀ pre-separator by Opsis AB is: 1.04.17

As of serial number SN 1513, the measuring system will be equipped with an alternative ¹⁴C 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 is based on the measuring principle of beta-attenuation.

The PM AMS OPSIS SM 200 for PM₁₀ 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 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 container has capacity for 40 filters.

For sampling inlet, a PM₁₀-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 16.67 l/min = 1.0 m³/h. As an alternate, the use of TSP, PM_{2.5} and PM₁₀-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 (option C). 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.

Certificate:
0000027201_01 / 21 January 2016

Certification of OPSIS SM 200 with pre-seperator for PM₁₀ 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: 936/801013/A of 29 January 2003,
TÜV Immissionsschutz und Energiesysteme GmbH, Cologne,
Publication: BAnz. 15 May 2003, No. 90, p. 10742, Chapter III No. 1.1,
Announcement by UBA from 22 April 2003

Supplementary test:

Test report: 936/21201592/A of 5 July 2005,
TÜV Immissionsschutz und Energiesysteme GmbH, Cologne,
Publication: BAnz. 29 October 2005, No. 206, p. 15702, Chapter IV No. 1.1,
Announcement by UBA from 25 July 2005

Initial certification according to EN 15267:

Certificate No. 0000027201: 9 February 2011
Validity of the certificate until: 25 January 2016
Statement of TÜV Rheinland Energie und Umwelt GmbH of 6 October 2010,
Test report: 936/21201592/A of 5 July 2005,
TÜV Immissionsschutz und Energiesysteme GmbH, Cologne,
Publication: BAnz. 26 January 2011, No. 14, p. 296, Chapter IV, Notification 4,
Announcement by UBA from 10 January 2011

Notification according to EN 15267:

Statement of TÜV Rheinland Energie und Umwelt GmbH of 30 September 2013,
Publication: BAnz AT 01.04.2014 B12, chapter VI, notification 30,
Announcement by UBA from 27 February 2014 (alternative ¹⁴C radiation source)

Renewal of the certificate:

Certificate No : 0000027201_01: 21 January 2016
Validity of the certificate: 25 January 2021

Results of the equivalence test for the demonstration of equivalence according to EN 12341:1998

Type-approval test from 936/801013/A of 2003-01-29

Candidate 1 vs. Candidate 2

Candidates	Test site	No. of values	STD s_a	Student-Factor t_f	Confidence interval CI_{95}
SN			$\mu\text{g}/\text{m}^3$		$\mu\text{g}/\text{m}^3$
285 / 288	Parking lot Köln	39	1.96	2.026	3.96
	Wesseling	62	1.46	2.000	2.91
	Mechernich	114	1.28	1.981	2.54
	Brühl	45	1.38	2.017	2.78
	Total	260	1.46	1.969	2.87

Candidate vs. Reference

SN 285	No. of values N	Slope m	Offset b	R ²
Parking lot Köln	17	1.0374	-1.8928	0.978
Wesseling	40	1.0043	2.0421	0.958
Mechernich	66	1.0345	-0.4712	0.950
Brühl	18	1.0062	-1.3519	0.956

SN 288	No. of values N	Slope m	Offset b	R ²
Parking lot Köln	17	1.0829	-2.697	0.986
Wesseling	40	1.0193	1.8582	0.976
Mechernich	66	1.0243	-0.5352	0.951
Brühl	18	0.9209	0.0913	0.962

Candidate	No. of values N	Slope m	Offset b	R ²
SN 285	141	1.0177	0.0478	0.956
SN 288	141	1.0211	-0.1718	0.959

Candidates	Test site	No. of values	STD s_a	Student-Factor t_f	Confidence interval CI_{95}
SN	Furulund		$\mu\text{g}/\text{m}^3$		$\mu\text{g}/\text{m}^3$
1110 / 1112		104	1.14	1.983	2.27
1110 / 276		80	1.65	1.991	3.29
1112 / 276		80	1.41	1.991	2.81

Candidate vs. Reference

Candidate	No. of values N	Slope m	Offset b	R^2
SN 1110	43	1.0946	-1.0318	0.973
SN 1112	43	1.0490	0.3288	0.977
SN 276	34	1.0271	0.5794	0.954