CERTIFICATE

of Product Conformity (QAL1)

Certificate No.: 0000027201_03

Certified AMS:	SM 200 with PM_{10} pre-separator
Manufacturer:	Opsis AB Skytteskogsvägen 16 24402 Furulund Sweden
Test Institute:	TÜV Rheinland Energy & Environment GmbH

This is to certify that the AMS has been tested and found to comply with the standards VDI 4202-1 (2010), VDI 4203-3 (2010), EN 16450 (2017), EN 12341 (1998), as well as EN 15267-1 (2009) and EN 15267-2 (2023).

Certification is awarded in respect of the conditions stated in this certificate (this certificate contains 9 pages).
The present certificate replaces certificate 0000027201_02 dated 25 January 2021.

TÜVRheinland® CERTIFIED
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 Environment Agency

Dessau, 22 January 2026

This certificate will expire on:
25 January 2031

TÜV Rheinland
Energy & Environment GmbH
Cologne, 21 January 2026

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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.

Test report:	936/21201592/A dated 5 July 2005
Initial certification:	26 January 2011
Expiry date:	25 January 2031
Certificate:	Renewal (of previous certificate 0000027201_02 of 25 January 2021 valid until 25 January 2026)
Publication:	BAnz. 29 October 2005, No. 206, p. 15700, chapter IV No. 1.1

Approved application

The tested AMS is suitable for continuous immission measurement of PM_{10} in stationary use.

The suitability of the AMS for this application was assessed on the basis of a laboratory test and a field test at five different locations with different time 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 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 936/21201592/A dated 5 July 2005 of TÜV 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: BAnz. 29 October 2005, No. 206, p. 15700, chapter IV No. 1.1, Announcement by UBA dated 25 July 2005:

AMS designation:
OPSIS SM 200 with PM_{10} pre-separator

Manufacturer:
OPSIS AB, S-24402 Furulund, Sweden

Field of application:
For continuous monitoring of suspended particulate matter, PM_{10} fraction, in ambient air from stationary sources

Measuring ranges during the performance test:
0 – 200 µg/m³

Software version:
Version 1.03 (OPSIS SM 200 (new))

Notes:
1. Supplementary testing as regards Federal Environment Agency notice of 22 April 2003 (BAnz. p. 10742)
2. The 2 instrument versions can easily be distinguished based on their serial numbers:
   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 by Aeris AB, Box 244, 244 02 Furulund, Sweden.
4. The measuring system must be operated inside a lockable measurement container.
5. The linearity test for the radiometric measurement requires various reference foils provided by the instrument manufacturer.
6. The intake pipe must be purged with ambient air all the way up to the analyser (option C).
7. The instrument must be calibrated with the gravimetric PM_{10} reference method described in standard EN 12341.

Test Laboratory:
TÜV Immissionsschutz und Energiesysteme GmbH, Cologne
TÜV Rheinland Group

Test Report:
Report No.: 936/21201592/A dated 5 July 2005

Publication in the German Federal Gazette: BAnz. 26. Januar 2011, Nr. 14, S. 294, Chap. IV notification 4, Announcement by UBA dated 10 January 2011:

4 Notification as regards Federal Environment Agency (UBA) notices of 25 July 2005 (BAnz. p. 15702, chapter IV number 1.1) and of 3 August 2009 (BAnz. p. 2929, chapter III notification 13)

The OPSIS SM 200 measuring system with PM_{10} pre-separator manufactured by OPSIS AB satisfies the requirements specified by EN 12341. Furthermore, the manufacturing process and the quality management for the OPSIS SM 200 measuring system for PM_{10} meets the requirements of EN 15267.
The test report on performance testing is available on the internet at www.qal1.de.

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

Publication in the German Federal Gazette: BAnz AT 01.04.2014 B12, Chap. VI notification 30, Announcement by UBA dated 27 February 2014:

30 Notification as regards Federal Environment Agency (UBA) notices of 25 July 2005 (p. 15700, chapter IV number 1.1) and of 10 January 2011 (BAnz. p. 294, chapter IV notification 4)

The latest software version of the SM 200 measuring system with PM_{10} pre-separator manufactured by Opsis AB is: 1.04.17

Instruments with S/N 1513 and higher are equipped with a ^{14}C light source manufactured by Eckert & Ziegler, Germany.

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

Publication in the German Federal Gazette: BAnz AT 11.04.2022 B10, Chap. VI notification 20, Announcement by UBA dated 9 March 2022:

20 Notification as regards Federal Environment Agency (UBA) notices of 25 July 2005 (BAnz. p. 15700, chapter IV number 1.1) and of 27 February 2014 (BAnz AT 01.04.2014 B12, chapter VI notification 30)

The current software version for the measuring device SM 200 with PM_{10} pre-separator of the company OPSIS AB is:
1.04 R:20

Statement issued by TÜV Rheinland Energy GmbH dated 13 September 2021

Certified product

This certificate 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_{10} 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/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 cartridges hold 40 filters.

For sampling inlet, a PM_{10}-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 16.67 l/min = 1.0 m³/h. As an alternate, the use of TSP, $PM_{2,5}$ and PM_{10}-sampling inlets is also possible.

The intake pipe connects the sample head to the sampling and measurement unit. 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 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 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 & Environment 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 as well as the certification mark remains property of TÜV Rheinland Energy & Environment 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 & Environment 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**.

History of documents
Certification of SM 200 PM_{10} is based on the documents listed below and the regular, continuous monitoring of the Quality Management System of the manufacturer:

Basic test
Test report: 936/801013/A dated 29 January 2003
TÜV Immissionsschutz und Energiesysteme GmbH
Publication: BAnz. 15 May 2003, No. 90, p. 10742, chapter III number 1.1
UBA announcement dated 22 April 2003

Supplementary testing
Test report: 936/21201592/A dated 5 July 2005
TÜV Immissionsschutz und Energiesysteme GmbH
Publication: BAnz. 29 October 2005, No. 206, p. 15700, chapter IV number 1.1
UBA announcement dated 25 July 2005

Initial certification according to EN 15267
Certificate No. 0000027201_00: 9 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: 936/21201592/A dated 5 July 2005
Publication: BAnz. 26 January 2011, No. 14, p. 294, chapter IV number 4
UBA announcement dated 10 January 2011

Notifications
Statement issued by TÜV Rheinland Energie und Umwelt GmbH dated 30 September 2013
Publication: BAnz AT 01.04.2014 B12, chapter VI notification 30
UBA announcement dated 27 February 2014
(Soft- and hardware changes)

Renewal of certificates
Certificate No. 0000027201_01: 21 January 2016
Expiry date of the certificate: 25 January 2021

Renewal of certificates
Certificate No. 0000027201_02: 25 January 2021
Expiry date of the certificate: 25 January 2026

Notifications
Statement issued by TÜV Rheinland Energy GmbH dated 13 September 2021
Publication: BAnz AT 11.04.2022 B10, chapter VI notification 20
UBA announcement dated 9 March 2022
(Software changes)

Renewal of certificates
Certificate No. 0000027201_03: 26 January 2026
Expiry date of the certificate: 25 January 2031

Results of the equivalence test performed to demonstrate equivalence as defined in EN 12341:1998

Performance test reported in 936/801013/A dated 29 January 2003

Test specimen 1 vs. Test specimen 2

Tested instruments	Location	Number of measurements	Standard deviation s_a	Student factor t_f	Confidence level CI_{95}
SN			µg/m³		µg/m³
285 / 288	Parking lot Cologne	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

Test specimens vs. Reference

S/N 285	Number of measurements N	Slope m	Axis intercept b	R^2
Parking lot Cologne	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

S/N 288	Number of measurements N	Slope m	Axis intercept b	R^2
Parking lot Cologne	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

Test instruments	Number of measurements N	Slope m	Axis intercept b	R^2
SN 285	141	1.0177	0.0478	0.956
SN 288	141	1.0211	-0.1718	0.959

Supplementary test reported in 936/21201592/A dated 5 July 2005

Test specimen 1 vs. Test specimen 2

Tested instruments	Location	Number of measurements	Standard deviation s_a	Student factor t_f	Confidence level CI_{95}
SN	Furulund		µg/m³		µg/m³
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

Test specimens vs. Reference

Test instruments	Number of measurements N	Slope m	Axis intercept 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