

**SLOVENSKI STANDARD**  
**SIST EN 15267-2:2023****01-september-2023****Nadomešča:**  
**SIST EN 15267-2:2009**

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**Kakovost zraka - Ocenjevanje opreme za monitoring kakovosti zraka - 2. del:  
Začetno ocenjevanje proizvajalčevega sistema vodenja kakovosti in nadzor nad  
procesi proizvodnje po certificiranju**

Air quality - Assessment of air quality monitoring equipment - Part 2: Initial assessment of the manufacturer's quality management system and post certification surveillance for the manufacturing process

Luftbeschaffenheit - Beurteilung von Einrichtungen zur Überwachung der Luftbeschaffenheit - Teil 2: Erstmalige Beurteilung des Qualitätsmanagementsystems des Herstellers und Überwachung des Herstellungsprozesses nach der Zertifizierung

Qualité de l'air - Évaluation des équipements de surveillance de la qualité de l'air - Partie 2 : Évaluation initiale du système de management de la qualité du fabricant et surveillance après certification du procédé de fabrication

**Ta slovenski standard je istoveten z: EN 15267-2:2023****ICS:**

03.100.70	Sistemi vodenja	Management systems
13.040.99	Drugi standardi v zvezi s kakovostjo zraka	Other standards related to air quality

**SIST EN 15267-2:2023****en,fr,de**



EUROPEAN STANDARD

EN 15267-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

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ICS 03.100.70; 13.040.99

Supersedes EN 15267-2:2009

English Version

## Air quality - Assessment of air quality monitoring equipment - Part 2: Initial assessment of the manufacturer's quality management system and post certification surveillance for the manufacturing process

Qualité de l'air - Évaluation des équipements de surveillance de la qualité de l'air - Partie 2 : Évaluation initiale du système de management de la qualité du fabricant et surveillance après certification du procédé de fabrication

Luftbeschaffenheit - Beurteilung von Einrichtungen zur Überwachung der Luftbeschaffenheit - Teil 2: Erstmalige Beurteilung des Qualitätsmanagementsystems des Herstellers und Überwachung des Herstellungsprozesses nach der Zertifizierung

This European Standard was approved by CEN on 24 April 2023.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## European foreword

This document (EN 15267-2:2023) has been prepared by Technical Committee CEN/TC 264 “Air quality”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 15267-2:2009.

The main changes with respect to the previous edition are listed below:

- a) The title of the revised EN 15267 series has been clarified to avoid the impression that all parts deal with the certification of automated measuring systems. The title has been generalized so that specifically Part 1 and Part 2 are also applicable to other air quality monitoring equipment.
- b) The title of revised EN 15267-2 has been clarified to make it clear that Part 2 deals only with the manufacturing process as part of the certification of air quality monitoring equipment.
- c) The revised EN 15267-2 is based on EN ISO 9001:2015 and is identically structured. It provides guidance on the application of EN ISO 9001:2015 with respect to AQME. It supplements EN ISO 9001:2015 by providing clarification and additional information. However, it does not restate all the provisions of EN ISO 9001:2015 and users are reminded of the need to comply with all of the relevant criteria detailed in EN ISO 9001:2015.
- d) The basic contents of EN 15267-2:2009 were largely adopted, updated and inserted into the structure of EN ISO 9001:2015.
- e) The term “competent body” has been deleted and replaced throughout the text by the term “certification body”.

This document is Part 2 of a series of European Standards:

- EN 15267-1, *Air quality — Assessment of air quality monitoring equipment — Part 1: General principles of certification*
- EN 15267-2, *Air quality — Assessment of air quality monitoring equipment — Part 2: Initial assessment of the manufacturer’s quality management system and post certification surveillance for the manufacturing process*
- EN 15267-3, *Air quality — Assessment of air quality monitoring equipment — Part 3: Performance criteria and test procedures for stationary automated measuring systems for continuous monitoring of emissions from stationary sources*
- EN 15267-4, *Air quality — Assessment of air quality monitoring equipment — Part 4: Performance criteria and test procedures for portable automated measuring systems for periodic measurements of emissions from stationary sources*

**EN 15267-2:2023 (E)**

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

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[SIST EN 15267-2:2023](https://standards.iteh.ai/catalog/standards/sist/226c7951-f5ed-4db0-8003-47fef077a7d1/sist-en-15267-2-2023)

<https://standards.iteh.ai/catalog/standards/sist/226c7951-f5ed-4db0-8003-47fef077a7d1/sist-en-15267-2-2023>

## Introduction

The assessment of air quality monitoring equipment (AQME) supports the requirements of certain Directives of the European Union (EU), which require, either directly or indirectly, that this equipment comply with performance criteria, maximum permissible measurement uncertainties and testing requirements. These Directives include the Directive 2010/75/EU on industrial emissions (IED), Directive (EU) 2015/2193 on medium combustion plants and the Directive 2008/50/EC on ambient air quality and cleaner air for Europe. This document can also be applied e.g. in the context of other national legislation.

The assessment of AQME consists of the following sequential stages:

- a) performance test;
- b) initial assessment of the manufacturer's quality management system (QMS);
- c) certification;
- d) surveillance for the manufacturing process.

AQME typically undergo changes during its product life. It is essential to ensure that such changes do not alter the AQME such that they no longer conform with the certified performance. In order to control such changes of AQME this document specifies the requirements for

- the manufacturer's QMS,
- the initial assessment of the manufacturer's production control, and
- the continuing surveillance of the effect on performance of certified AQME of subsequent changes.

This document is based on EN ISO 9001 and supplements the requirements of EN ISO 9001 for the manufacturer's quality management system, the initial assessment of the manufacturer's production control and the continuing surveillance of the effect of subsequent changes on the performance of certified AQME. This document does not preclude the use of other QMS that are compatible with the objectives of EN ISO 9001.

**EN 15267-2:2023 (E)****1 Scope**

This document specifies requirements for the manufacturer's quality management system (QMS). Furthermore, it specifies requirements for the initial assessment of the manufacturer's production control and the continuing surveillance of the effect of subsequent changes on the performance of certified air quality monitoring equipment (AQME).

This document also serves as a reference document for auditing the manufacturer's QMS.

This document applies only in combination with EN ISO 9001.

**2 Normative references**

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 15267-1:2023, *Air Quality - Assessment of air quality monitoring equipment - Part 1: General principle of certification*

**3 Terms and definitions**

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <https://www.electropedia.org/>

**3.1  
air quality monitoring equipment****AQME**

automated measuring system or data acquisition and handling system

[SOURCE: EN 15267-1:2023, 3.1]

**3.2  
automated measuring system****AMS**

entirety of all measuring instruments and additional devices for obtaining a result of measurement

Note 1 to entry: The term "automated measuring system" applies to stationary and portable AMS.

Note 2 to entry: Apart from the actual measuring device (the analyser), an AMS can include facilities for taking samples (e.g. probe, sample gas lines, flow meters and regulator, delivery pump) and for sample conditioning (e.g. dust filter, pre-separator for interferences, cooler, converter). This definition also includes testing and adjusting devices that are required for functional checks and QAL3 procedures and, if applicable, for commissioning.

Note 3 to entry: The term "automated measuring system" (AMS) is typically used in Europe. The terms "continuous emission monitoring system" (CEM) and "continuous ambient-air-quality monitoring system" (CAM) are also typically used in the UK and USA.

[SOURCE: FprEN 15267-1:2023, 3.2]



### 3.3

#### **portable automated measuring system**

##### **P-AMS**

automated measuring system which is in a condition or application to be moved from one to another measurement site to obtain measurement results for a short measurement period

Note 1 to entry: The measurement period is typically 8 h for a day.

Note 2 to entry: The P-AMS can be configured at the measurement site for the special application but can be also set-up in a van or mobile container. The probe and the sample gas lines are installed often just before the measurement task is started.

[SOURCE: EN 15267-1:2023, 3.3]

### 3.4

#### **data acquisition and handling system**

##### **DAHS**

system, which automatically receives, processes, stores and outputs data from automated measuring systems

[SOURCE: EN 15267-1:2023, 3.4]

### 3.5

#### **product**

air quality monitoring equipment

[SOURCE: EN 15267-1:2023, 3.5]

### 3.6

#### **testing laboratory**

laboratory carrying out the performance tests

[SOURCE: EN 15267-1:2023, 3.6]

### 3.7

#### **manufacturer**

organisation, situated at a stated location or locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product and its certification, and undertakes all obligations in that connection

Note 1 to entry: The term “manufacturer” is used instead of “organisation” as used in EN ISO 9001. For the purpose of this document they are interchangeable.

[SOURCE: EN 15267-1:2023, 3.7]

### 3.8

#### **certification body**

third-party conformity assessment body operating certification schemes

[SOURCE: EN ISO/IEC 17065:2012, 3.12]

**EN 15267-2:2023 (E)****3.9****technical file**

record of the reference documents and changes to the reference documents

[SOURCE: EN 15267-1:2023, 3.9]

**3.10****reference document**

document that controls the manufacture and design of air quality monitoring equipment and is referenced in the test report

Note 1 to entry: Reference documents can include drawings, specifications, instructions and computer code.

[SOURCE: EN 15267-1:2023, 3.10]

**3.11****related document**

document not referenced in the test report

Note 1 to entry: A related document can be used, for example, for the detailed manufacture of component parts.

[SOURCE: EN 15267-1:2023, 3.11]

**3.12****certification range**

range over which the automated measuring system is tested and certified for compliance with the relevant performance criteria

Note 1 to entry: The lower limit of the certification range is usually zero.

Note 2 to entry: Generally, the lower the certification range, the better the performance of the AMS. Also an AMS typically performs satisfactorily at higher values over the measurement range.

[SOURCE: EN 15267-1:2023, 3.12]

**3.13****surveillance**

systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity

[SOURCE: EN ISO/IEC 17000:2020, 8.1]

**3.14****competent authority**

organisation which implements the requirements of legislation and regulates installations

[SOURCE: EN 15267-1:2023, 3.14]

Note 1 to entry: For the purposes of this document surveillance focuses on the manufacturer's QMS to ensure that AQME continue to comply with the standard to which they are certified.