

ÕHUKVALITEET. ÕHUKVALITEEDI SEIRESEADMETE  
HINDAMINE. OSA 2: TOOTJA  
KVALITEEDIJUHTIMISSÜSTEEMI ESMANE HINDAMINE  
JA TOOTMISPROTSESSI SERTIFITSEERIMISE JÄRGNE  
JÄRELEVALVE

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>See Eesti standard EVS-EN 15267-2:2023 sisaldab Euroopa standardi EN 15267-2:2023 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 05.07.2023.</p> <p>Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN 15267-2:2023 consists of the English text of the European standard EN 15267-2:2023.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 05.07.2023.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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ICS 03.100.70, 13.040.99

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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

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

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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 re-state 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*

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.

## 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.

## 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]