

ÕHU VÕI TOOTE SISETEMPERATUURI MÕÕTMISE
TERMOMEETRID TEMPERATUURITUNDLIKE KAUPADE
TRANSPORTIMISEL, LADUSTAMISEL JA LEVITAMISEL.
KATSED, TOIMIMINE, SOBIVUS

Thermometers for measuring the ambient or internal
temperature for the transport, storage and
distribution of temperature sensitive goods - Tests,
performance, suitability

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 13485:2024 sisaldab Euroopa standardi EN 13485:2023 ingliskeelset teksti. Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 13.12.2023. Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	This Estonian standard EVS-EN 13485:2024 consists of the English text of the European standard EN 13485:2023. This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 13.12.2023. The standard is available from the Estonian Centre for Standardisation and Accreditation.
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English Version

Thermometers for measuring the ambient or internal
temperature for the transport, storage and distribution of
temperature sensitive goods - Tests, performance,
suitability

Thermomètres de mesure de la température ambiante
ou interne pour le transport, le stockage et la
distribution des marchandises thermosensibles -
Essais, performance, aptitude à l'emploi

Thermometer zur Messung der Umgebungs- und
Innentemperatur für den Transport, die Lagerung und
die Verteilung von temperaturempfindlichen
Produkten - Prüfung, Leistung, Gebrauchstauglichkeit

This European Standard was approved by CEN on 20 November 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 13485:2023) has been prepared by Technical Committee CEN/TC 423 “Means of measuring and/or recording temperature in the cold chain”, 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 June 2024, and conflicting national standards shall be withdrawn at the latest by June 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 13485:2001.

EN 13485:2023 includes the following significant technical changes with respect to EN 13485:2001:

- a) clarification of the scope;
- b) complete revision of Clause 4;
- c) addition of class 0,2 to the document;
- d) revision of 5.1;
- e) revision of 5.3 with examples to clarify the process;
- f) revision of 5.5.1 and 5.5.3;
- g) update of Clauses 7 and 8 according to the revised clauses;
- h) revision of Clause 9;
- i) addition of Annex B regarding expected operation time and storage capacity;
- j) addition of Annex C regarding examples for temperature conditions;
- k) addition of Annex D regarding example of a life cycle sheet;
- l) addition of Annex E as guideline to the verification process;
- m) addition of Annex F as guideline to determine the expanded uncertainty.

This document meets the objectives of the following directives:

- 92/1/EEC of January 15, 1992 of the Commission of the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption; (Commission Regulation (EC) No 37/2005 of 12 January 2005 on the monitoring of temperatures in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption with EEA relevance);
- 92/2/EEC of January 13, 1992 of the Commission laying down the sampling procedure and the community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption;

- 93/43/EEC of June 14, 1993 of the Council of the hygiene of foodstuffs and in particular on “temperature control criteria” (Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs).

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.

1 Scope

This document specifies the technical and functional characteristics for all types of thermometers (electronic, mechanical, etc.) for equipping the means used for the transport, storage and distribution of temperature sensitive goods and for measuring the ambient or internal temperature of the products between $-80\text{ }^{\circ}\text{C}$ and $+85\text{ }^{\circ}\text{C}$.

It specifies the test methods which allow the verification of the equipment's conformity to suitability and performance requirements.

It applies to the whole thermometer and indicating device(s). The temperature sensor(s) can be integrated into the thermometer or remote from it (wired or wireless external temperature sensor(s)).

It does not specify the location of the thermometer and its sensors with respect to types of usage such as transport, storage and distribution.

NOTE Examples for the transport, storage and distribution of temperature sensitive goods between $-80\text{ }^{\circ}\text{C}$ and $+85\text{ }^{\circ}\text{C}$ include chilled, frozen, deep frozen and quick-frozen food; ice cream; fresh and hot food; pharmaceuticals; blood and organs; chemicals; biologicals; electronic and mechanical devices; flowers, plants and bulbs; raw materials and liquids; animals; art and furnishings.

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 13486, *Temperature recorders and thermometers for measuring the ambient or internal temperature for the transport, storage and distribution of temperature sensitive goods — Periodic verification*

EN 60068-2-27, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

EN 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements*

EN IEC 61000-6-2, *Electromagnetic compatibility (EMC) — Part 6-2: Generic standards — Immunity for industrial environments*

EN IEC 61000-6-3, *Electromagnetic compatibility (EMC) — Part 6-3: Generic standards — Emission standard for residential, commercial and light-industrial environments*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

JCGM 200:2012, *International Vocabulary of Metrology — Basic and general concepts and associated terms (VIM)*¹

¹ Available at: <https://www.bipm.org/en/committees/jc/jcgm/publications>