



SLOVENSKI STANDARD
oSIST prEN 13485:2022
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Termometri za merjenje temperature okolice ali notranje temperature pri prevozu, skladiščenju in distribuciji toplotno občutljivega blaga - Preskusi, značilnosti, ustreznost

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

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

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

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ICS:

17.200.20	Instrumenti za merjenje temperature	Temperature-measuring instruments
67.260	Tovarne in oprema za živilsko industrijo	Plants and equipment for the food industry

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

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

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 423.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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prEN 13485:2022 (E)**European foreword**

This document (prEN 13485:2022) 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 document is currently submitted to the CEN enquiry.

This document will supersede EN 13485:2001.

In comparison with the previous edition, the following technical modifications have been made:

- a) clarification of the scope;
- b) Clause 4 has been completely revised;
- c) addition of class 0,2 to the document;
- d) Clause 5.1 has been revised;
- e) Clause 5.3 has been revised with examples to clarify the process;
- f) Clause 5.5.1 and 5.5.3 have been revised;
- g) Clauses 7 and 8 have been updated according to the revised clauses;
- h) Clause 9 has been revised;
- 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 has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association.

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).

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 °C and $+85\text{ °C}$.

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

It applies to the whole indicator-temperature sensor(s). The temperature sensor(s) can be integrated into the thermometer or remote from it (external temperature sensor(s)).

It does not define 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 °C and $+85\text{ °C}$ 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 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 61000-6-2, *Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity for industrial environments*

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

EN 13486, *Temperature recorders and thermometers for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice cream - Periodic verification*

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

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:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

prEN 13485:2022 (E)**3.1
quantity**

<measurement> attribute of a phenomenon, body or substance that may be distinguished qualitatively and determined quantitatively

EXAMPLE Temperature.

[SOURCE: VIM [1]]

**3.2
unit**

<measurement> particular quantity, defined and adopted by convention, with which other quantities of the same kind are compared in order to express their magnitudes relative to that quantity

EXAMPLE The unit of temperature used in this document is “degree Celsius”.

[SOURCE: VIM [1]]

**3.3
symbol of a unit**

conventional sign designating a unit of measurement

EXAMPLE °C is the symbol of “degree Celsius”.

[SOURCE: VIM [1]]

**3.4
value**

<quantity> magnitude of a particular quantity generally expressed as a unit of measurement multiplied by a number

EXAMPLE 15 °C

[SOURCE: VIM [1]]

**3.5
true value**

<quantity> value consistent with the definition of a given particular quantity

Note 1 to entry: This is a value that would be obtained by a perfect measurement.

[SOURCE: VIM [1]]

**3.6
measurement**

set of operations having the object of determining a value of a quantity

**3.7
measurand**

particular quantity subject to a measurement

EXAMPLE Temperature.

[SOURCE: VIM [1]]

3.8**influence quantity**

quantity that is not the measurand but that affects the result of the measurement

[SOURCE: VIM [1]]

3.9**indication**

<measuring instrument> value of a quantity provided by a measuring instrument

[SOURCE: VIM [1]]

3.10**accuracy**

<measurement> closeness of the agreement between the result of a measurement and a true value of the measurand

[SOURCE: VIM [1]]

3.11**uncertainty**

<measurement> parameter, associated with the result of a measurement, which characterizes the dispersion of the values that could reasonably be attributed to the measurand

[SOURCE: VIM [1]]

3.12**error**

<measurement> result of a measurement minus a true value of the measurand

[SOURCE: VIM [1]]

3.13**relative error**

error of a measurement divided by a true value of the measurand

[SOURCE: VIM [1]]

3.14**measuring instrument**

device intended to be used to make measurements, alone or in conjunction with supplementary device(s)

[SOURCE: VIM [1]]

3.15**displaying device****indicating device**

part of a measuring instrument that displays an indication

[SOURCE: VIM [1]]

prEN 13485:2022 (E)**3.16****thermometer**

any device to measure and display temperature

3.17**temperature sensor**

element of a measuring instrument or measuring chain that is directly affected by the temperature

3.18**external temperature sensor**

sensor which measures a temperature independent of the enclosure of the indicating device

3.19**internal temperature sensor**

sensor which measures the temperature of the enclosure of the thermometer

3.20**scale**

<measuring instrument> ordered set of marks, together with any numbering, forming part of a displaying device of a measuring instrument

[SOURCE: VIM [1]]

3.21**scale division**

part of a scale between two successive scale marks

[SOURCE: VIM [1]]

3.22**adjustment**

<measuring instrument> operation of bringing a measuring instrument into a state of performance suitable for its use

[SOURCE: VIM [1]]

3.23**user adjustment**

<measuring instrument> adjustment employing the means at the disposal of the user

[SOURCE: VIM [1]]

3.24**span**

modulus of the difference between the two limits of a nominal range

EXAMPLE For a nominal range of - 35 °C to + 25 °C, the span is 60 °C.

[SOURCE: VIM [1]]

3.25**measuring range****working range**

set of values for which the error of a measuring instrument is intended to lie within specified limits

[SOURCE: VIM [1]]

3.26**rated operating conditions**

conditions of use for which specified metrological characteristics of a measuring instrument are intended to lie within given limits

[SOURCE: VIM [1]]

3.27**limiting conditions**

extreme conditions that a measuring instrument is required to withstand without damage, and without degradation of specified metrological characteristics when it is subsequently operated under its rated operating conditions

[SOURCE: VIM [1]]

3.28**reference conditions**

conditions of use prescribed for testing the performance of a measuring instrument or for comparison of results of measurements

[SOURCE: VIM [1]]

3.29**resolution**

<displaying device> smallest difference between indications of a displaying device that can be meaningfully distinguished

[SOURCE: VIM [1]]

3.30**response time**

time interval between the instant when a stimulus is subjected to a specified abrupt change and the instant when the response reaches and remains within specified limits around its final steady value

[SOURCE: VIM [1]]

3.31**storage and transport conditions**

extreme conditions which a non-operational measuring instrument can withstand without damage and without degradation of specified metrological characteristics when it is subsequently operated under its rated operating conditions

3.32**chilled food**

food which has been subjected to cooling (without freezing) and is intended to be maintained at low temperature

prEN 13485:2022 (E)**3.33****frozen food**

food which has been subjected to a freezing process specially designed to preserve the wholesomeness and quality of the product

3.34**deep-frozen or quick-frozen food**

food which has been subjected to a quick freezing process

3.35**verification**

confirmation and provision of evidence that the specified requirements have been fulfilled

Note 1 to entry: In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

Note 2 to entry: The result of verification leads to a decision to either restore to service, perform adjustments, repair, downgrade, or declare obsolete. A written trace of the verification performed is kept on the measuring instrument's individual record.

[SOURCE: EN ISO 9000:2015, 3.8.12]

4 Requirements**4.1 General**

Manufacturers shall make recommendations on the specification of ancillary equipment in order to meet the performance requirements of this document.

The manufacturer shall define the use of the transport, storage and operational conditions. Examples are given in the informative Annex C.

NOTE Further information is included in EN 60721-3-3 and EN 60721-2-3.

The manufacturer shall verify the defined requirements of his applications.

If the system would have the possibilities to prevent and/or detect manipulation and to prove the validity of the data, it can be validated according to the relevant chapters in EN 12830.

4.2 Measuring range

- The temperature sensor shall be able to measure the air and/or product temperature in the measuring range that it is defined by the manufacturer;
- The thermometers shall be able to indicate the air and/or product temperature which is extended twice the maximum permissible error for the maximum defined class of the temperature sensor stated by the manufacturer in both directions, see 4.8.2;
- For climate classes, see the relevant legislation and quality specifications.