



SLOVENSKI STANDARD

oSIST prEN ISO 6876:2025

01-januar-2025

Zobozdravstvo - Endodontski zapiralni materiali (ISO/DIS 6876:2024)

Dentistry - Endodontic sealing material (ISO/DIS 6876:2024)

Zahnheilkunde - Endodontische Versiegelungswerkstoffe (ISO/DIS 6876:2024)

Médecine bucco-dentaire - Matériaux de scellement endodontique (ISO/DIS 6876:2024)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and Restorative Materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 6876:2012), which has been technically revised.

The main changes to the previous edition are as follows:

- inclusion of endodontic sealing materials, other than orthograde endodontic sealing material used with endodontic obturating materials;
- definition and classification of two types of endodontic sealing materials;
- a change of mould material from gypsum to metal or other non-reactive materials for the setting time test;
- augmented test methods for flow, working time, setting times, and solubility for clarity and convenience;
- addition of ISO 13116 for the determination of radio-opacity as a normative reference;
- addition of an alternative test method for working time in [Annex A](#);
- addition of information on the moulds for tests in Annex B.

Any feedback or questions on this document should be directed to the user's national standards body.

A complete listing of these bodies can be found at www.iso.org/members.html.

ISO/DIS 6876:2024(en)**Introduction**

The following should be taken into account when using this document: specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this document but it is recommended that, for the assessment of such biological risks, reference be made to ISO 7405 and ISO 10993-1.

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Dentistry — Endodontic sealing materials

1 Scope

This document specifies the classification, requirements and test methods for endodontic sealing materials used in dentistry.

This document is applicable to materials used for conventional orthograde endodontic sealing (Type 1) and materials used for other endodontic sealing procedures including apexification, perforation filling, resorption, or retrograde root-end filling (Type 2).

The Type 2 endodontic sealing materials may be used for vital pulp therapy. However, this document does not address or include requirements for vital pulp therapy.

This document does not specify requirements or test methods for sterility.

NOTE 1 Reference to applicable national regulations and internationally accepted pharmacopoeias can be made.

NOTE 2 National requirements regarding sterilization processes, if available, can be used. Standards on methods of validating sterilization processes are also available: ISO 11737-1, ISO 11737-2 and ISO 11737-3.

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.

ISO 1942, *Dentistry — Vocabulary*

ISO 3630-1:2019, *Dentistry — Endodontic instruments — Part 1: General requirements*

ISO 13116:2014, *Dentistry — Test method for determining radio-opacity of materials*

ISO 6877:2021, *Dentistry — Endodontic obturating materials*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 3630-1 and the following 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/>

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3.1

endodontic obturating material

radio-opaque dental material used in the form of a point, carrier-based obturating device, or injection material used in combination with an *endodontic sealing material* (3.2) to fill voids and seal root canals during orthograde obturation

Note 1 to entry: Endodontic obturating points are used with endodontic sealers.

[SOURCE: ISO 6877:2021, 3.1, modified]

3.2

endodontic sealing material

materials intended to permanently seal the root canal system usually in combination with endodontic obturating points during 'orthograde obturation' and used for other endodontic sealing procedures including apexification, perforation filling, resorption or retrograde root-end filling

3.3

working time

period of time, measured from the start of mixing, or dispensing of a single paste, during which it is possible to manipulate the material without any adverse effects on its properties (7.4)

3.4

setting time

time measured from the start of mixing, or dispensing of a single paste, after which no indentation change is observed with the Gillmore apparatus (7.5.2.2)

3.5

radio-opacity

property of obstructing the passage of radiant energy, such as x-rays, the representative areas appearing grey or white on an exposed film or digital sensor image

4 Classification

For the purposes of this document, *endodontic sealing materials* (3.2) are classified into the following types based on their intended use:

- a) Type 1: *endodontic sealing material* (3.2) that is usually used in conjunction with *endodontic obturating material* (3.1) to fill and seal the root canal system intended for "orthograde use", i.e. a root filling placed from the coronal part of a tooth.

NOTE 1 In ISO 6877:2021, Clause 3.15, an *endodontic sealing material* is termed an 'endodontic sealer'.

- b) Type 2: *endodontic sealing material* (3.2) used for other endodontic sealing procedures including apexification, perforation repair, (internal and external) resorption, or retrograde root-end filling.

NOTE 2 Type 2 materials can selectively be used to seal root canal orifices in conjunction with other endodontic sealing materials.

NOTE 3 Type 2 materials generally have higher viscosity than Type 1 materials.

5 Requirements

5.1 General

When tested in accordance with the test methods specified in [Clause 7](#), Type 1 and Type 2 materials shall comply with the performance requirements specified in [Table 1](#).