

Dentistry - Endodontic sealing material (ISO 6876:2025)

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NATIONAL FOREWORD

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ICS 11.060.10

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EUROPEAN STANDARD

EN ISO 6876

NORME EUROPÉENNE

EUROPÄISCHE NORM

November 2025

ICS 11.060.10

Supersedes EN ISO 6876:2012

English Version

Dentistry - Endodontic sealing material (ISO 6876:2025)

Médecine bucco-dentaire - Matériaux de scellement
endodontique (ISO 6876:2025)

Zahnheilkunde - Endodontische
Versiegelungswerkstoffe (ISO 6876:2025)

This European Standard was approved by CEN on 28 September 2025.

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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

European foreword

This document (EN ISO 6876:2025) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 "Dentistry" 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of an identical text or by endorsement, at the latest by May 2026, and conflicting national standards shall be withdrawn at the latest by May 2026.

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 ISO 6876:2012.

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

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Endorsement notice

The text of ISO 6876:2025 has been approved by CEN as EN ISO 6876:2025 without any modification.

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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 document 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).

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For an explanation of 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 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:

- endodontic sealing materials, other than orthograde endodontic sealing material used with endodontic obturating materials, have been included;
- two types of endodontic sealing materials have been defined and classified;
- mould material has been changed from gypsum to metal or other non-reactive materials for the setting time test;
- test methods for flow, working time, setting times and solubility have been augmented for clarity and convenience;
- ISO 13116 for the determination of radiopacity has been added as a normative reference;
- an alternative test method has been added for working time to [Annex A](#).

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.

Introduction

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 treatment 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 pharmacopeias 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, *Dentistry — Endodontic instruments — Part 1: General requirements*

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