
Zobozdravstvo - Endodontski instrumenti - 1. del: Splošne zahteve (ISO/DIS 3630-1:2026)

Dentistry - Endodontic instruments - Part 1: General requirements (ISO/DIS 3630-1:2026)

Zahnheilkunde - Endodontische Instrumente - Teil 1: Allgemeine Anforderungen (ISO/DIS 3630-1:2026)

Médecine bucco-dentaire - Instruments d'endodontie - Partie 1: Prescriptions générales (ISO/DIS 3630-1:2026)

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DRAFT International Standard

ISO/DIS 3630-1

Dentistry — Endodontic instruments —

Part 1: General requirements

Médecine bucco-dentaire — Instruments d'endodontie —

Partie 1: Exigences générales

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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 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 4, Dental instruments, Working group WG 9, Endodontic instruments 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 3630-1:2019), which has been technically revised.

The main changes compared to the previous edition are as follows:

- clarification of vocabulary and symbols to make it harmonize with the other parts of the 3630 standards.

A list of all parts in the ISO 3630 series can be found on the ISO website.

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 3630-1:2026(en)**Introduction**

This document specifies general requirements and test methods for endodontic instruments. Other parts of the ISO 3630 series provide the specific requirements and test methods for specific endodontic instruments (enlargers, compactors, auxiliary instruments, shaping and cleaning instruments, and ultrasonic inserts). It also provides test methods for accuracy of electronic apex locators.

With the current use of nickel-titanium alloys for the manufacture of endodontic instruments, a need for adequate expertise in their safe use is recommended. Cyclic fatigue and subsequent breakage of engine-driven -titanium endodontic instruments remain an issue when practicing endodontic treatment. A test method is provided to evaluate the fatigue resistance of such instruments using a custom-made device.

This document provides guidance and information for the proper use of these instruments.

The sizes of the endodontic obturating points (cones) specified in ISO 6877 Dentistry — Endodontic obturating materials should coordinate with the corresponding sizes for the endodontic instruments which are specified in all parts of the ISO 3630 series.

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Dentistry — Endodontic instruments —

Part 1: General requirements

1 Scope

This document specifies general requirements and test methods for endodontic instruments used for specific purposes, e.g., enlargers, compactors, auxiliary instruments, shaping and cleaning instruments, and ultrasonic inserts. In addition, it covers general size designations, colour-coding, identification symbols, and product information including marking, labeling, packaging, and instructions for use.

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 554, *Standard atmospheres for conditioning and/or testing — Specifications*

ISO 1797, *Dentistry — Shanks for rotary and oscillating instruments*

ISO 1942, *Dentistry — Vocabulary*

ISO 3630-2, *Dentistry — Endodontic instruments — Part 2: Enlargers*

ISO 3630-3, *Dentistry — Endodontic instruments — Part 3: Compactors*

ISO 3630-4, *Dentistry — Endodontic instruments — Part 4: Auxiliary instruments*

ISO 3630-5, *Dentistry — Endodontic instruments — Part 5: Shaping and cleaning instruments*

ISO 3630-7, *Dentistry — Endodontic instruments — Part 7: Ultra sonic inserts*

ISO 3630-8, *Dentistry — Endodontic instruments — Part 8: Accuracy of electronic apex locators*

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

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

ISO 13402:2025, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure*