Dentistry - Endodontic instruments - Part 1: General requirements (ISO 3630-1:2019)

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 3630-1:2019 sisaldab Euroopa standardi EN ISO 3630-1:2019 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 3630-1:2019 consists of the English text of the European standard EN ISO 3630-1:2019.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 09.10.2019.	Date of Availability of the European standard is 09.10.2019.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EN ISO 3630-1

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English Version

Dentistry - Endodontic instruments - Part 1: General requirements (ISO 3630-1:2019)

Médecine bucco-dentaire - Instruments d'endodontie - Partie 1: Exigences générales (ISO 3630-1:2019)

Zahnheilkunde - Endodontische Instrumente - Teil 1: Allgemeine Anforderungen (ISO 3630-1:2019)

This European Standard was approved by CEN on 4 June 2019.

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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 3630-1:2019) 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of an identical text or by endorsement, at the latest by April 2020, and conflicting national standards shall be withdrawn at the latest by April 2020.

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 3630-1:2008.

According to the CEN-CENELEC Internal Regulations, the national standards organizations 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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 3630-1:2019 has been approved by CEN as EN ISO 3630-1:2019 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 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).

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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 4, *Dental instruments.*

This third edition cancels and replaces the second edition (ISO 3630-1:2008), which has been technically revised.

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

— reorganization with the intention of presenting the requirements and test methods for endodontic instruments in an orderly manner;

— change of the main element of the title of the ISO 3630 series to "Endodontic instruments";

— addition of requirements for the current use of Nickel-Titanium;

— clarification of the option for the handle shape for the manufacturer;

— addition of the new identification symbols in Figure 10.

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.

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 six areas of endodontics (enlargers, compactors, auxiliary instruments, shaping and cleaning instruments, numeric coding system and ultrasonic inserts).

With current use of Nickel-Titanium alloys for manufacture of endodontic instruments a need for adequate expertise in their safe use is recommended. This document does not attempt to provide information for proper use of any instruments.

The sizes of the endodontic obturating points (cones) specified in ISO 6877 should be aligned with the corresponding sizes for endodontic instruments specified in all parts of the ISO 3630 series.

Dentistry — Endodontic instruments —

Part 1:
General requirements

1 Scope

This document specifies general requirements and test methods for endodontic instruments used for endodontic purposes, e.g. enlargers, compactors, accessory instruments, shaping and cleaning instruments, and a numeric coding system. In addition, it covers general size designations, color-coding, packaging, and identification symbols.

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, *Endodontic instruments — Part 2: Enlargers*

ISO 3630-3, *Endodontic instruments — Part 3: Compactors: pluggers and spreaders*

ISO 3630-4, *Root canal instruments — Part 4: Auxiliary instruments*

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

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

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, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 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 http://www.electropedia.org/