

**Dentistry - Root-canal instruments - Part 1:
General requirements and test methods**

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EESTI STANDARDI EESSÕNA

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English Version

**Dentistry - Root-canal instruments - Part 1: General
requirements and test methods (ISO 3630-1:2008)**

Art dentaire - Instruments pour canaux radiculaires - Partie
1: Exigences générales et méthodes d'essai (ISO 3630-
1:2008)

Zahnheilkunde - Wurzelkanalinstrumente - Teil 1:
Allgemeine Anforderungen und Prüfverfahren (ISO 3630-
1:2008)

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Foreword

This document (EN ISO 3630-1:2008) 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of an identical text or by endorsement, at the latest by August 2008, and conflicting national standards shall be withdrawn at the latest by August 2008.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 3630-1:1994.

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Endorsement notice

The text of ISO 3630-1:2008 has been approved by CEN as a EN ISO 3630-1:2008 without any modification.

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Introduction

The reorganization of ISO 3630 is intended to present the requirements and test methods for root-canal instruments in an orderly manner. This part of ISO 3630 defines general requirements and test methods. Subsequent parts provide the specific requirements and test methods, if applicable, for two areas of endodontic procedures. These parts are enlargers, condensers and auxiliary instruments.

With current use of nickel-titanium (Ni-Ti) alloys for manufacture of root canal instruments a need for adequate expertise in their safe use is recommended. Instruments made of Ni-Ti can be easily broken near the tip if manufacturer's cautions are not understood and practiced. This part of ISO 3630 does not attempt to provide information for proper use of any instruments.

The sizes of the root-canal obturating points (cones) specified in ISO 6877^[4] have to be aligned with the corresponding sizes for root-canal instruments specified in ISO 3630.

Dentistry — Root-canal instruments —

Part 1: General requirements and test methods

1 Scope

This part of ISO 3630 specifies general requirements and test methods for root-canal instruments used for endodontic purposes, e.g. enlargers, shaping and cleaning instruments, condensers, and accessory instruments. In addition it covers general size designations, colour coding, packaging and identification symbols.

2 Normative references

The following referenced documents are indispensable for the application 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 1942, *Dental vocabulary* (all parts)

ISO 1797-1:1992, *Dental rotary instruments — Shanks — Part 1: Shanks made of metals*

ISO 1797-2:1992, *Dental rotary instruments — Shanks — Part 2: Shanks made of plastics*

ISO 3630-2:2000, *Dental root-canal instruments — Part 2: Enlargers*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 6360-2, *Dentistry — Number coding system for rotary instruments — Part 2: Shapes*

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

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

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

3 Terms, definitions and symbols

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.