

**Dentistry - Endodontic instruments - Part 5: Shaping  
and cleaning instruments (ISO 3630-5:2011)**

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## EESTI STANDARDI EESSÕNA

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<p>Käesolev Eesti standard EVS-EN ISO 3630-5:2011 sisaldab Euroopa standardi EN ISO 3630-5:2011 ingliskeelset teksti.</p> <p>Standard on kinnitatud Eesti Standardikeskuse 31.10.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.10.2011.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 3630-5:2011 consists of the English text of the European standard EN ISO 3630-5:2011.</p> <p>This standard is ratified with the order of Estonian Centre for Standardisation dated 31.10.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.</p> <p>Date of Availability of the European standard text 01.10.2011.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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English Version

## Dentistry - Endodontic instruments - Part 5: Shaping and cleaning instruments (ISO 3630-5:2011)

Médecine bucco-dentaire - Instruments d'endodontie -  
Partie 5: Instruments de mise en forme et de nettoyage  
(ISO 3630-5:2011)

Zahnheilkunde - Endodontische Instrumente - Teil 5: Form-  
und Reinigungsinstrumente (ISO 3630-5:2011)

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## Foreword

This document (EN ISO 3630-5:2011) 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of an identical text or by endorsement, at the latest by April 2012, and conflicting national standards shall be withdrawn at the latest by April 2012.

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### Endorsement notice

The text of ISO 3630-5:2011 has been approved by CEN as a EN ISO 3630-5:2011 without any modification.

## Introduction

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this part of ISO 3630. However, in assessing possible biological or toxicological hazards, it is recommended that reference be made to ISO 10993-1 and ISO 7405.

Attention is drawn to ISO 6360 (all parts), which specifies a 15-digit number for the identification of dental rotary instruments of all types.

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# Dentistry — Endodontic instruments —

## Part 5: Shaping and cleaning instruments

### 1 Scope

This part of ISO 3630 specifies requirements and test methods for hand-held or mechanically operated shaping and cleaning instruments used to perform root canal procedures not cited in ISO 3630-1, ISO 3630-2, ISO 3630-3 or ISO 3630-4.

This part of ISO 3630 specifies requirements for size, marking, product designation, safety considerations, labelling and packaging.

### 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 1942, *Dentistry — Vocabulary*

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

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and ISO 3630-1 apply.

### 4 Classification

For the purposes of this document, shaping and cleaning instruments are classified into five types, as specified in ISO 3630-1:2008, Clause 4.

### 5 Requirements

#### 5.1 Material

The materials used for the working part, the shank and the handle of shaping and cleaning instruments are left to the discretion of the manufacturer but shall meet the requirements of ISO 3630-1:2008, 5.7.

#### 5.2 Dimensions

##### 5.2.1 General

The dimensions for the nominal diameter and taper of shaping and cleaning instruments shall meet the requirements of ISO 3630-1:2008, Clause 5.

The allowable tolerance for the identified diameters of Types 2, 3, 4, and 5 shall be less than 50 % of the difference between the preceding size and the next larger size instrument of the available brand sizes.