Dentistry - Endodontic instruments - Part 2: Enlargers

Dentistry - Endodontic instruments - Part 2: Enlargers (ISO 3630-2:2013)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 3630-2:2013 sisaldab Euroopa standardi EN ISO 3630-2:2013 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 3630-2:2013 consists of the English text of the European standard EN ISO 3630-2:2013.
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 17.04.2013.	Date of Availability of the European standard is 17.04.2013.
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.

ICS 11.060.20

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 3630-2

April 2013

ICS 11.060.20

Supersedes EN ISO 3630-2:2000

English Version

Dentistry - Endodontic instruments - Part 2: Enlargers (ISO 3630-2:2013)

Médecine bucco-dentaire - Instruments d'endodontie - Partie 2: Élargisseurs (ISO 3630-2:2013)

Zahnheilkunde - Endodontische Instrumente - Teil 2: Erweiterer (ISO 3630-2:2013)

This European Standard was approved by CEN on 11 April 2013.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 3630-2:2013: E

Foreword

This document (EN ISO 3630-2:2013) 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 October 2013, and conflicting national standards shall be withdrawn at the latest by October 2013.

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 3630-2:2000.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 3630-2:2013 has been approved by CEN as EN ISO 3630-2:2013 without any modification.

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Introduction

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard but it is recommended that, in assessing possible biological or toxicological hazards, 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.

Dentistry — Endodontic instruments —

Part 2:
Enlargers

1 Scope

This part of ISO 3630 specifies requirements for enlargers not cited in ISO 3630-1, ISO 3630-3, ISO 3630-4 or ISO 3630-5.

This part of ISO 3630 specifies requirements for size, marking, product designation, safety considerations, and their labelling and packaging, including the instructions for use.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1797-1, *Dentistry — Shanks for rotary instruments — Part 1: Shanks made of metals*

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

ISO 1942, *Dentistry — Vocabulary*

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

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, ISO 3630-1 and the following apply.

3.1.1
enlarger
hand- or power-operated endodontic instrument used for improving access to the root canal by enlarging its coronal opening