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Standards

Irish Standard
I.S. EN ISO 3630-2:2013

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

I.S. EN ISO 3630-2:2013

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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:
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Contents

Page

Foreword.....3

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of an identical text or by endorsement, at the latest by October 2013, and conflicting national standards shall be withdrawn at the latest by October 2013.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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INTERNATIONAL
STANDARD

ISO
3630-2

Third edition
2013-04-15

**Dentistry — Endodontic
instruments —**

**Part 2:
Enlargers**

*Médecine bucco-dentaire — Instruments d'endodontie —
Partie 2: Élargisseurs*



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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms, definitions and symbols	1
3.1 Terms and definitions.....	1
3.2 Symbols.....	2
4 Classification	2
4.1 Enlarger Type B1.....	2
4.2 Enlarger Type B2.....	2
4.3 Enlarger Type G.....	2
4.4 Enlarger Type M.....	2
4.5 Enlarger Type P.....	2
5 Requirements	2
5.1 Materials.....	2
5.2 Dimensions, designation and number of blades.....	3
5.3 Mechanical requirements.....	9
6 Sampling	10
7 Testing	10
7.1 General.....	10
7.2 Dimensions.....	10
7.3 Resistance to fracture by twisting and angular deflection.....	11
7.4 Resistance to bending.....	11
7.5 Resistance to fatigue.....	11
7.6 Fracture location.....	11
8 Designation, marking and identification	13
9 Packaging	14
10 Labelling	14
Bibliography	15

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 3630-2 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This third edition cancels and replaces the second edition (ISO 3630-2:2000), which has been technically revised.

The following changes were made:

- a) tolerances for diameter measurements were aligned;
- b) test procedures were aligned with ISO 3630-1.

ISO 3630 consists of the following parts, under the general title *Dentistry — Endodontic instruments*:

- *Part 1: General requirements and test methods*
- *Part 2: Enlargers*
- *Part 3: Condensers, pluggers and spreaders*
- *Part 4: Auxiliary instruments*
- *Part 5: Shaping and cleaning instruments*

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

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