

Dentistry - Endodontic instruments - Part 2: Enlargers
(ISO 3630-2:2023)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 3630-2:2023 sisaldab Euroopa standardi EN ISO 3630-2:2023 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 3630-2:2023 consists of the English text of the European standard EN ISO 3630-2:2023.
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English Version

Dentistry - Endodontic instruments - Part 2: Enlargers
(ISO 3630-2:2023)

Médecine bucco-dentaire - Instruments d'endodontie -
Partie 2: Élargisseurs (ISO 3630-2:2023)

Zahnheilkunde - Endodontische Instrumente - Teil 2:
Erweiterer (ISO 3630-2:2023)

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 3630-2:2023) 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of an identical text or by endorsement, at the latest by August 2023, and conflicting national standards shall be withdrawn at the latest by August 2023.

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 3630-2:2013.

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Endorsement notice

The text of ISO 3630-2:2023 has been approved by CEN as EN ISO 3630-2:2023 without any modification.

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	1
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
5.1.1 Shank	2
5.1.2 Working part	3
5.2 Dimensions, designation and number of blades	3
5.3 Mechanical requirements	8
5.3.1 Resistance to fracture by twisting and angular deflection	8
5.3.2 Resistance to bending	8
5.3.3 Resistance to fatigue	8
5.3.4 Fracture location	8
5.4 Resistance to reprocessing	9
6 Sampling	9
7 Testing	9
7.1 General	9
7.2 Dimensions	9
7.2.1 Diameters	9
7.2.2 Tip	9
7.2.3 Shank	9
7.2.4 Lengths	9
7.2.5 Blades	9
7.3 Resistance to fracture by twisting and angular deflection	9
7.4 Resistance to bending	10
7.5 Resistance to fatigue	10
7.6 Fracture location	10
7.7 Test report	11
8 Product information	12
8.1 Marking	12
8.2 Labelling	12
8.3 Packaging	12
8.4 Instructions for use	12
Bibliography	13

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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This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 3630-2:2013), which has been technically revised.

The main changes are as follows:

- symbols have been redefined;
- the test method has been redefined;
- this document has been harmonized with other parts of the ISO 3630 series.

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

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

The nominal size, D , is not utilized in this document because of the nature of the enlargers. Therefore, d_m , represents the nominal size for this document only.

Dentistry — Endodontic instruments —

Part 2: Enlargers

1 Scope

This document specifies the requirements for enlargers not cited in ISO 3630-1, ISO 3630-3, ISO 3630-4, ISO 3630-5, ISO TR 3630-6¹⁾ or ISO 3630-7²⁾.

This document specifies the requirements for size, marking, product designation, safety considerations, and labelling and packaging, including the instructions for use.

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 1797, *Dentistry — Shanks for rotary and oscillating instruments*

ISO 1942, *Dentistry — Vocabulary*

ISO 3630-1:2019, *Dentistry — Endodontic instruments — 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.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1.1

enlarger

engine-driven endodontic instrument used to improve access to the root canal system by enlarging its coronal opening

3.2 Symbols

For the purposes of this document, the following symbols apply. All dimensions are in millimetres (see [Figures 1](#) to [5](#), [Figure 7](#) and [Tables 1](#) to [8](#)).

1) Under preparation. Stage at the time of publication: ISO/CD TR 3630-6:2023.

2) Under preparation. Stage at the time of publication: ISO/PWI 3630-7:2023.