

<b>STN</b>	<b>Stomatológia</b> <b>Endodontické nástroje</b> <b>Časť 2: Rozširovače (ISO 3630-2: 2023)</b>	<b>STN</b> <b>EN ISO 3630-2</b>  85 6032
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Dentistry - Endodontic instruments - Part 2: Enlargers (ISO 3630-2:2023)

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 05/23

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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)

This European Standard was approved by CEN on 24 December 2022.

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**EN ISO 3630-2:2023 (E)**

<b>Contents</b>	<b>Page</b>
<b>European foreword.....</b>	<b>3</b>

## **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of an identical text or by endorsement, at the latest by August 2023, and conflicting national standards shall be withdrawn at the latest by August 2023.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.

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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.

# INTERNATIONAL STANDARD

# ISO 3630-2

Fourth edition  
2023-02

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## Dentistry — Endodontic instruments —

### Part 2: Enlargers

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



Reference number  
ISO 3630-2:2023(E)

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CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
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# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms, definitions and symbols</b> .....	<b>1</b>
3.1 Terms and definitions.....	1
3.2 Symbols.....	1
<b>4 Classification</b> .....	<b>2</b>
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
<b>5 Requirements</b> .....	<b>2</b>
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
<b>6 Sampling</b> .....	<b>9</b>
<b>7 Testing</b> .....	<b>9</b>
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
<b>8 Product information</b> .....	<b>12</b>
8.1 Marking.....	12
8.2 Labelling.....	12
8.3 Packaging.....	12
8.4 Instructions for use.....	12
<b>Bibliography</b> .....	<b>13</b>

## ISO 3630-2:2023(E)

### 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](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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](http://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 3630-6<sup>1)</sup> or ISO 3630-7<sup>2)</sup>.

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*

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**

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.