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Dentistry - Materials for dental instruments - Part 2:  
Polymers (ISO 21850-2:2025)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>See Eesti standard EVS-EN ISO 21850-2:2025 sisaldab Euroopa standardi EN ISO 21850-2:2025 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 25.06.2025.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN ISO 21850-2:2025 consists of the English text of the European standard EN ISO 21850-2:2025.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 25.06.2025.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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EUROPEAN STANDARD

EN ISO 21850-2

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

## Dentistry - Materials for dental instruments - Part 2: Polymers (ISO 21850-2:2025)

Médecine bucco-dentaire - Matériaux pour instruments  
dentaires - Partie 2: Polymères (ISO 21850-2:2025)

Zahnheilkunde - Werkstoffe für Dentalinstrumente -  
Teil 2: Polymere (ISO 21850-2:2025)

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

## European foreword

This document (EN ISO 21850-2:2025) 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of an identical text or by endorsement, at the latest by December 2025, and conflicting national standards shall be withdrawn at the latest by December 2025.

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 has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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## Endorsement notice

The text of ISO 21850-2:2025 has been approved by CEN as EN ISO 21850-2:2025 without any modification.

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## Foreword

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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 document 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)).

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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).

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## Introduction

An increasing number of newly developed dental surgery techniques make use of procedures like dental implant placements. The market for dental instruments is also growing rapidly, alongside demand for new and better instruments.

This document is intended to support the harmonization of approval procedures and the reduction of costs caused by separate approval and test procedures in different countries with regard to the polymer materials used in dental instruments.

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# Dentistry — Materials for dental instruments —

## Part 2: Polymers

### 1 Scope

This document specifies polymers commonly used in manufacturing dental instruments.

It is applicable to polymers used to manufacture either an entire instrument or part of an instrument.

It is applicable to single-use and reusable dental instruments, whether they are connected to a power-driven system or not.

This document does not apply to oral appliances and devices (e.g. splints, mouthpieces, crowns, bridges, implants), to instruments used long-term in the mouth of the patient or to devices and instruments not made of polymers.

This document contains a selection of polymers suitable for use in the manufacture of dental instruments.

### 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 472, *Plastics — Vocabulary*

ISO 1043-1, *Plastics — Symbols and abbreviated terms — Part 1: Basic polymers and their special characteristics*

ISO 1942, *Dentistry — Vocabulary*

ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 472, ISO 1942 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

##### **dental instrument**

hand-held tool specially designed for use in dentistry

[SOURCE: ISO 1942:2020, 3.4.3.5]