

SLOVENSKI STANDARD oSIST prEN ISO 9873:2019

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Zobozdravstvo - Intraoralna ogledala (ISO/FDIS 9873:2018)

Dentistry - Intra-oral mirrors (ISO/FDIS 9873:2018)

iTeh STANDARD PREVIEW

Médecine bucco-dentaire - Miroirs endobuccaux (ISO/FDIS 9873:2018)

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Dentistry — Intra-oral mirrors

Médecine bucco-dentaire — Miroirs endobuccaux

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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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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.

This document was prepared by Technical Committee ISO/TC 106, *Denitsry*, Subcommittee SC 4, *Dental instruments*.

This fourth edition cancels and replaces the third edition (ISO 9873:2017), which has been technically revised.

The main changes compared to the previous edition are as follows:

- recommendation for maximum length of intra-oral mirror has been reduced from 178 mm to 173 mm in 4.1.1:
- requirement for distortion has been added in 4.3.4;
- requirement for handle has been clarified in 4.3.6;
- resistance to reprocessing requirement has been clarified in 4.4;
- requirement for UDI code has been added in <u>Clause 6</u>.

Introduction

This document specifies requirements for intra-oral viewing and retracting instruments which are in common use in dentistry.

However, it is well known that there are also other types of intra-oral mirrors in use which have different designs and/or are made of different materials. Amongst these other types are mirrors with a polished metal reflecting surface (as opposed to a coated glass surface).

Standardization of these other types can form the subject of future work.

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Dentistry — Intra-oral mirrors

1 Scope

This document specifies requirements and test methods for reusable intra-oral mirrors with a coated glass reflecting surface used for dental purposes in the oral cavity.

In addition, specific requirements for metallic casing and metallic handles are given.

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 263, ISO inch screw threads — General plan and selection for screws, bolts and nuts — Diameter range 0,06 to 6 inch

ISO 724, ISO general-purpose metric screw threads — Basic dimensions

ISO 965-1, ISO general purpose metric screw threads — Tolerances — Part 1: Principles and basic data

ISO 1942, Dentistry — Vocabulary

ISO 5864, ISO inch screw threads — Allowances and tolerances

ISO 17664, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices $\frac{1}{1000}$

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

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

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

3.1

intra-oral mirror

mouth mirror

handheld dental instrument for intra-oral inspection or inspection and tissue retraction generally comprising the mirror head and the mirror handle

Note 1 to entry: See Figure 1.

3.2

mirror head

assembly comprising a glass reflective surface, casing, packing (if present) and stem

3.3

stem

part of the intra-oral mirror connecting the reflecting surface to the handle

3.4

reflecting surface

layer applied to the mirror glass for the purpose of reflecting light

3.5

reflecting back surface

reflecting layer coated onto the back surface of the mirror glass so that the image can be observed through the glass

3.6

reflecting front surface

reflecting layer coated onto the front surface of the mirror glass so that the image can be observed with no intervening glass layer

3.7

plane mirror

intra-oral mirror whose reflective surface is flat

3.8

magnifying mirror

intra-oral mirror whose reflective surface is concave to produce an enlarged image of the object observed

3.9

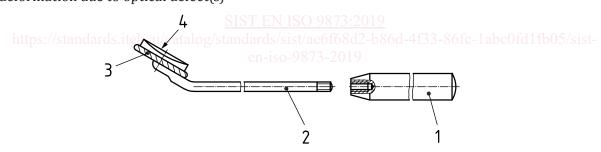
viewing surface

surface of the mirror glass, excluding the bevel, not enclosed by the metal casing

3.10

distortion

image deformation due to optical defect(s)



Key

- 1 handle
- 2 stem
- 3 mirror head
- 4 reflecting surface

Figure 1 — Designation of intra-oral mirror parts

4 Requirements

4.1 Dimensions and designations

4.1.1 Overall length

The maximum overall length of an intra-oral mirror is at the manufacturer's discretion but it should be noted that there is a possiility that overall lengths in excess of 173 mm cause difficulty in containment within a sterilization cassette.