

STN	Stomatológia Sinusový membránový elevátor (ISO 19490: 2025)	STN EN ISO 19490 85 6384
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Dentistry - Sinus membrane elevator (ISO 19490:2025)

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. 11/25

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19490:2025)

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EUROPÄISCHES KOMITEE FÜR NORMUNG**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

EN ISO 19490:2025 (E)

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European foreword

This document (EN ISO 19490:2025) 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of an identical text or by endorsement, at the latest by February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.

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International Standard

ISO 19490

Dentistry — Sinus membrane elevator

Médecine bucco-dentaire — Élévateur de membrane sinusienne

**Second edition
2025-07**

ISO 19490:2025(en)



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ISO 19490:2025(en)**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 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).

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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

This second edition cancels and replaces the first edition (ISO 19490:2017), which has been technically revised.

The main changes are as follows:

- a new reference (ISO 4865-1) has been added to [Clause 2](#);
- a new reference (ISO 17664-1) has been added to [Clause 2](#);
- requirements and test methods have been referenced from ISO 4865-1;
- overall lengths have been reduced from 178 mm to 173 mm;
- a new figure has been added in Type 1 classification;
- marking, labelling and packaging specifications from ISO 4865-1 have been added to [Clause 7](#);
- instruction for use from ISO 4865-1 and ISO 17664-1 have been added to [Clause 8](#).

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ISO 19490:2025(en)**Introduction**

A sinus membrane elevator is a dental instrument. It is used during the placement of dental implants for sinus floor lifting to augment the vertical bone thickness. This document addresses these types of sinus membrane elevator.

Dentistry — Sinus membrane elevator

1 Scope

This document specifies requirements and their test methods for sinus membrane elevators used during the placement of dental implants for sinus floor lifting. It also specifies the requirements for their marking and labelling.

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 1942, *Dentistry — Vocabulary*

ISO 4865-1:2023, *Dentistry — General requirements of hand instruments — Part 1: Non-hinged hand instruments*

ISO 13504, *Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment*

ISO 16443, *Dentistry — Vocabulary for dental implants systems and related procedure*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

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