

STN	Stomatológia Fluoridové laky (ISO 17730: 2020)	STN EN ISO 17730 85 6375
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Dentistry - Fluoride varnishes (ISO 17730:2020)

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. 12/20

Obsahuje: EN ISO 17730:2020, ISO 17730:2020

Oznámením tejto normy sa ruší
STN EN ISO 17730 (85 6375) z mája 2015

132133

EUROPEAN STANDARD

EN ISO 17730

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 2020

ICS 97.170

Supersedes EN ISO 17730:2014

English Version

Dentistry - Fluoride varnishes (ISO 17730:2020)Médecine bucco-dentaire - Vernis fluorés (ISO
17730:2020)

Zahnheilkunde - Fluoridlacke (ISO 17730:2020)

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EN ISO 17730:2020 (E)

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European foreword

This document (EN ISO 17730:2020) 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of an identical text or by endorsement, at the latest by April 2021, and conflicting national standards shall be withdrawn at the latest by April 2021.

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The text of ISO 17730:2020 has been approved by CEN as EN ISO 17730:2020 without any modification.

INTERNATIONAL STANDARD

ISO
17730

Second edition
2020-09

Dentistry — Fluoride varnishes

Médecine bucco-dentaire — Vernis fluorés



Reference number
ISO 17730:2020(E)

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Published in Switzerland

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ISO 17730:2020(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).

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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral care products*, 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 second edition cancels and replaces the first edition (ISO 17730:2014), which has been technically revised.

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

- Additional subclause to indicate three samples are tested for total fluoride. Two aliquots are analysed for each sample.
- A requirement of minimum soluble fluoride release potential and a relevant test method have been added.

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

Fluoride varnishes are used in dentistry primarily for caries prevention and reduction of dentine hypersensitivity. Fluoride varnishes are applied in the oral cavity directly on the outer surfaces of teeth and fillings, and are intended to remain at least for several hours.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazards are not included in this document, but it is recommended that, for the assessment of possible biological or toxicological hazards, reference should be made to ISO 10993-1 and ISO 7405.

Dentistry — Fluoride varnishes

1 Scope

This document specifies requirements and test methods for total digestible fluoride content and a minimum soluble fluoride release potential in dental varnishes containing fluoride, intended for use in the oral cavity directly on the outer surfaces of teeth and fillings. It also specifies packaging and labelling requirements, including the instructions for use. This document covers fluoride varnishes to be applied by dental health care workers.

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 648:2008, *Laboratory glassware — Single-volume pipettes*

ISO 835:2007, *Laboratory glassware — Graduated pipettes*

ISO 1942, *Dentistry — Vocabulary*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 8601-2, *Date and time — Representations for information interchange — Part 2: Extensions*

ISO 19448, *Dentistry — Analysis of fluoride concentration in aqueous solutions by use of fluoride ion-selective electrode*

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