

## Dentistry - Fluoride varnishes (ISO 17730:2014)

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ICS 97.170

English Version

## Dentistry - Fluoride varnishes (ISO 17730:2014)

Médecine bucco-dentaire - Vernis fluorés (ISO 17730:2014)

Zahnheilkunde - Fluoridlacke (ISO 17730:2014)

This European Standard was approved by CEN on 23 August 2014.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

## Foreword

This document (EN ISO 17730:2014) 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of an identical text or by endorsement, at the latest by May 2015, and conflicting national standards shall be withdrawn at the latest by May 2015.

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### Endorsement notice

The text of ISO 17730:2014 has been approved by CEN as EN ISO 17730:2014 without any modification.

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## 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 hazard are not included in this International Standard, 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 International Standard specifies requirements and their test methods for total digestible fluoride content in dental varnishes containing fluoride, intended for use in the oral cavity directly on the outer surfaces of teeth and fillings. It also specifies the requirements for their packaging and labelling, including the instructions for use. This International Standard covers fluoride varnishes to be applied by dental health care workers.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

## 3 Terms and Definitions

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

### 3.1

#### **consumer packaging**

retail packaging

sales packaging

package, with labelling and contents as a sales unit to the user or consumer at the point of retail

Note 1 to entry: A consumer packaging can consist of a secondary packaging wrapping or container covering one or more primary packaging elements or, it can consist of a single primary packaging element containing the product.

Note 2 to entry: Adapted from ISO 21067:2007, definition 2.2.5.

### 3.2

#### **fluoride varnish**

dental product, in paintable liquid form containing fluoride compound for topical application to the outer surfaces of teeth and fillings, intended primarily to prevent tooth caries or reduce dentine hypersensitivity

### 3.3

#### **total fluoride**

mass percent of fluoride in the fluoride varnish