ICS 11.060.10 SLOVENSKÁ TECHNICKÁ NORMA November 2023

STN	**Stomatológia Hodnotenie antibakteriálnej aktivity zubných výplňových materiálov, fixačné cementy, pečatidlá a ortodontické lepiace alebo fixačné materiály (ISO 3990: 2023)**	**STN EN ISO 3990** 85 6409

Dentistry - Evaluation of antibacterial activity of dental restorative materials, luting materials, fissure sealants and orthodontic bonding or luting materials (ISO 3990:2023)

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. 10/23

Obsahuje: EN ISO 3990:2023, ISO 3990:2023

obsahuje farebné strany

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 3990

July 2023

ICS 11.060.10

English Version

Dentistry - Evaluation of antibacterial activity of dental restorative materials, luting materials, fissure sealants and orthodontic bonding or luting materials (ISO 3990:2023)

Médecine bucco-dentaire - Évaluation de l'activité antibactérienne des matériaux de restauration dentaire, matériaux de scellement, produits de comblement des fissures et matériaux de collage ou de scellement orthodontiques (ISO 3990:2023)

Zahnheilkunde - Bewertung der antibakteriellen Wirkung von dentalen Restaurationswerkstoffen, Befestigungszementen, Fissurenversieglern und kieferorthopädischen Klebe- oder Befestigungswerkstoffen (ISO 3990:2023)

This European Standard was approved by CEN on 1 July 2023.

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

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

Ref. No. EN ISO 3990:2023 E

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European foreword

This document (EN ISO 3990:2023) 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of an identical text or by endorsement, at the latest by January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.

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.

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Endorsement notice

The text of ISO 3990:2023 has been approved by CEN as EN ISO 3990:2023 without any modification.

INTERNATIONAL STANDARD

ISO 3990

First edition
2023-07

Dentistry — Evaluation of antibacterial activity of dental restorative materials, luting materials, fissure sealants and orthodontic bonding or luting materials

Médecine bucco-dentaire — Évaluation de l'activité antibactérienne des matériaux de restauration dentaire, matériaux de scellement, produits de comblement des fissures et matériaux de collage ou de scellement orthodontiques

Reference number
ISO 3990:2023(E)

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Published in Switzerland

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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 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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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, *Dentistry,* 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).

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

Due to the general applicability of *in vitro* tests for antibacterial activity and their widespread use in evaluating a large range of dental materials, it is the purpose of this document to define a scheme for testing which requires decisions to be made in a series of steps rather than to specify a single test. This should lead to the selection of the most appropriate test for a respective dental material to be evaluated.

Two categories of test are listed: extract test and direct contact test.

The choice of one or more of these categories depends upon the nature of the material to be evaluated, the potential site of use and the nature of the use of the respective material. Extract tests are primarily directed to substances leaching out from materials, whereas direct contact tests are directed to both, effects from leachable substances and surface effects. The choice of test then determines the details of the preparation of the samples to be tested, the preparation of the cultured bacteria or biofilms, and the way in which the bacteria or biofilms are exposed to the samples or their extracts.

Both categories of tests are intended to be first conducted toward planktonic cultures of bacteria and then, in case of positive results, toward bacterial biofilms.

This document proposes measurement of reduction of bacterial ability to replicate as the main method to assess antibacterial effects. Additionally, bacterial membrane damage can be assessed in order to further verify bacterial cell death and reductions in bacterial metabolic activity can be investigated as another measure of bacterial viability.

There are several means of producing results in each of these test categories. The investigator should be aware of the test categories and into which category a particular technique fits, in order to ensure the comparability with other results on similar materials both at the intra- and interlaboratory level.

Examples of quantitative test protocols for assessing reduction of bacterial ability to replicate by colony forming units (CFU) assay and for assessing bacterial membrane damage by flow cytometry and for investigating reductions in bacterial metabolic activity by MTT assay are given in this document along with guidance for the interpretation of the results.

INTERNATIONAL STANDARD **ISO 3990:2023(E)**

Dentistry — Evaluation of antibacterial activity of dental restorative materials, luting materials, fissure sealants and orthodontic bonding or luting materials

1 Scope

This document specifies test methods for the evaluation of dental restorative materials, luting materials, fissure sealants and orthodontic bonding or luting materials that are claimed by their respective manufacturers to exert “antibacterial” effects.

NOTE Materials for pulp capping (e.g. calcium hydroxide formulations), endodontic filling materials, dental implants or implant systems, nightguards and additive manufactured (e.g. 3D-printed) materials are not covered in this document.

This document does not cover tests on the effectiveness of sterilization or disinfection procedures. This document cannot be used to demonstrate a lack of microbial contamination of medical devices used in dentistry.

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 4049, *Dentistry — Polymer-based restorative materials*

ISO 6344-3, *Coated abrasives — Determination and designation of grain size distribution — Part 3: Microgrit sizes P240 to P5000*

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

ISO 9917-1, *Dentistry — Water-based cements — Part 1: Powder/liquid acid-base cements*

ISO 9917-2, *Dentistry — Water-based cements — Part 2: Resin-modified cements*

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

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-12, *Biological evaluation of medical devices — Part 12: Sample preparation and reference materials*

ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process*