SLOVENSKI STANDARD
SIST EN ISO 3990:2023

01-oktober-2023

Zobozdravstvo - Vrednotenje protibakterijskega delovanja zobozdravstvenih obnovitvenih materialov, zalivnih cementov, tesnilnih mas za fisure in ortodontskih lepilnih ali zalivnih materialov (ISO 3990:2023)

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

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

Ta slovenski standard je istoveten z: **EN ISO 3990:2023**

ICS:

11.060.10	Zobotehnični materiali	Dental materials

SIST EN ISO 3990:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 3990

July 2023

ICS 11.060.10

English Version

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

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

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

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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of an identical text or by endorsement, at the latest by January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.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

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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

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Foreword

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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,* 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.