



# SLOVENSKI STANDARD SIST EN ISO 3990:2023

01-oktober-2023

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**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**

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

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of an identical text or by endorsement, at the latest by January 2024, and conflicting national standards shall be withdrawn at the latest by January 2024.

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**Dentistry — Evaluation of  
antibacterial activity of dental  
restorative materials, luting materials,  
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*Médecine bucco-dentaire — Évaluation de l'activité antibactérienne  
des matériaux de restauration dentaire, matériaux de scellement,  
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## ISO 3990:2023(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.

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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](http://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.

