



SLOVENSKI STANDARD SIST EN ISO 10271:2020

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Nadomešča:
SIST EN ISO 10271:2011

Zobozdravstvo - Preskusne metode ugotavljanja korozije za kovinske materiale (ISO 10271:2020)

Dentistry - Corrosion test methods for metallic materials (ISO 10271:2020)

Zahnheilkunde - Korrosionsprüfverfahren für metallische Werkstoffe (ISO 10271:2020)

Médecine bucco-dentaire - Méthodes d'essai de corrosion des matériaux métalliques
(ISO 10271:2020)

Ta slovenski standard je istoveten z **EN ISO 10271:2020**

ICS:

11.060.10 Zobotehnični materiali Dental materials

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EUROPEAN STANDARD
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EUROPÄISCHE NORM

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September 2020

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Supersedes EN ISO 10271:2011

English Version

Dentistry - Corrosion test methods for metallic materials (ISO 10271:2020)

Médecine bucco-dentaire - Méthodes d'essai de
corrosion des matériaux métalliques (ISO 10271:2020)

Zahnheilkunde - Korrosionsprüfverfahren für
metallische Werkstoffe (ISO 10271:2020)

This European Standard was approved by CEN on 28 August 2020.

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European foreword

This document (EN ISO 10271:2020) 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of an identical text or by endorsement, at the latest by March 2021, and conflicting national standards shall be withdrawn at the latest by March 2021.

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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According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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INTERNATIONAL STANDARD

ISO 10271

Third edition
2020-08

Dentistry — Corrosion test methods for metallic materials

*Médecine bucco-dentaire — Méthodes d'essai de corrosion des
matériaux métalliques*

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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 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*, Subcommittee SC 2, *Prosthetic materials*, 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 third edition cancels and replaces the second edition (ISO 10271:2011), which has been technically revised. The main changes compared with the previous edition are as follows:

- in the Scope, the statement about this document not being applicable to “appliances for orthodontics” and “dental amalgam” has been removed;
- in 4.1.6.3, a NOTE has been added to the static immersion test method acknowledging that “measuring the total surface area of orthodontic appliances can be difficult” and, therefore, if required in the appropriate standard, “it is acceptable for the ion release for each element of a set of orthodontic brackets to be reported in terms of μg in seven days for a specified number of orthodontic brackets”;
- since sodium sulfide hydrate (approximately 35 % Na_2S) analytical grade is not available in every country, text was added to the appropriate test methods indicating that sodium sulfidenonahydrate ($\text{Na}_2\text{S}\cdot 9\text{H}_2\text{O}$), $\leq 98\%$ may be used;
- this document has been harmonized with ISO 22674:2016 by making changes in the preparation sections of the various test methods that reflect changes that were made for the preparation of metals supplied for metal-ceramic restorations in ISO 22674:2016;
- subclause 4.6 “Dental amalgam” has been added, which refers the user to ISO/TS 17988 when testing the corrosion behaviour of dental amalgam;
- subclause 4.7 “Crevice corrosion” has been added, which provides a test method to evaluate the susceptibility of a dental metallic material to crevice corrosion.

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.

ISO 10271:2020(E)

Introduction

This document was developed from the original Technical Report (ISO/TR 10271¹⁾) as a result of worldwide demand for standard test methods to determine the acceptability of metallic materials for oral restorations in relation to corrosion.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this document, but it is recommended that reference be made to ISO 10993-1 and ISO 7405 for assessing possible biological or toxicological hazards.

The testing of the corrosion behaviour of metallic materials in dentistry is complicated by the diversity of the materials themselves, their applications and the environment to which they are exposed. Variation occurs between devices and within the same device during the exposure time. The type of corrosion behaviour or effect can also vary with exposure time. Accordingly, it is not possible to specify a single test capable of covering all situations, nor is it a practical proposition to define a test for each situation. This document, therefore, gives detailed procedures for test methods that have been found to be of merit as evidenced by considerable use.

In the second edition, two new test methods were added. To supplement the existing static immersion test, a static immersion test with periodic analysis was added. A major reason for the addition of this test is that the rate of corrosion of most dental metallic materials varies over time. Thus, the aim of this supplementary test is to provide information on this variation in the corrosion of a dental metallic material. A classification scheme to interpret the rate of corrosion of a tested material with time (i.e. steady, decreasing, increasing) was not included as part of the static immersion test with periodic analysis. It is intended to monitor the use of the test through appropriate working groups of ISO/TC 106 to ascertain whether a classification scheme is needed in a future revision of this document. In this third edition, a classification scheme is still not included.

To supplement the sulfide tarnish test (cyclic immersion), a sulfide tarnish test (static immersion) was also added to the second edition of this document. This test has been used successfully for many years to evaluate the corrosion of silver alloys.

In addition, the second edition added [Annex A](#) which sets out a procedure for each element of the test system such that a consistent approach can be taken for the development of further test methods. Equally, it is recognized that any element can represent only the current recommendation, but changes in the future are unlikely to change the framework.

The third edition differs from the second by the removal of the statement in the Scope about the document not being applicable to “appliances for orthodontics” and “dental amalgam”. With the appliances for orthodontics change in mind, a NOTE was added to the static immersion test acknowledging that “measuring the total surface area of orthodontic appliances can be difficult” and stating that, if required in the appropriate standard, “it is acceptable for the ion release for each element of a set of orthodontic brackets to be reported in terms of μg in seven days for a specified number of orthodontic brackets”. Also, with reference to dental amalgam, a subclause on dental amalgam (see [4.6](#)) has been added, which refers the user to ISO/TS 17988 when testing the corrosion behaviour of dental amalgam. Additionally, there is a clarification statement that the test methods given in [4.1](#) to [4.5](#) are still not applicable to the evaluation of dental amalgam.

The third edition was harmonized with ISO 22674:2016 by adding to the preparation sections of the various test methods the following change concerning metals supplied for metal-ceramic restorations:

- “Following the manufacturer’s instructions, simulate the oxidation procedure and four ceramic firings at the highest temperature recommended for fusing ceramic to the metallic material. Remove and place the specimens on a ceramic plate (which is at room temperature) to cool to room temperature after the oxidation and ceramic firing simulation.”

1) Withdrawn document.