



SLOVENSKI STANDARD
oSIST prEN ISO 10271:2009
01-september-2009

Dentalni kovinski materiali - Preskusne metode ugotavljanja korozije (ISO/FDIS 10271:2009)

Dental metallic materials - Corrosion test methods (ISO/FDIS 10271:2009)

Zahnheilkunde - Korrosionsprüfverfahren (ISO/FDIS 10271:2009)

Produits dentaires métalliques - Méthodes pour les essais de corrosion (ISO/FDIS 10271:2009)

Ta slovenski standard je istoveten z: prEN ISO 10271

ICS:

11.060.10 Zlata in srebrna dentalna materiala Dental materials

oSIST prEN ISO 10271:2009

en,fr,de

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
prEN ISO 10271

May 2009

ICS 11.060.10

Will supersede EN ISO 10271:2001

English Version

Dental metallic materials - Corrosion test methods (ISO/FDIS 10271:2009)

Produits dentaires métalliques - Méthodes pour les essais de corrosion (ISO/FDIS 10271:2009)

Zahnheilkunde - Korrosionsprüfverfahren (ISO/FDIS 10271:2009)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 55.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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Foreword

This document (prEN ISO 10271:2009) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 10271:2001.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

Endorsement notice

The text of ISO/DIS 10271:2009 has been approved by CEN as a prEN ISO 10271:2009 without any modification.

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DRAFT INTERNATIONAL STANDARD ISO/DIS 10271

ISO/TC 106/SC 2

Secretariat: ANSI

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2009-10-07

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Dental metallic materials — Corrosion test methods

Produits dentaires métalliques — Méthodes pour les essais de corrosion

[Revision of first edition (ISO 10271:2001) and ISO 10271:2001/Cor.1:2005]

ICS 11.060.10

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ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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ISO/DIS 10271

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ISO/CD 10271

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 10271 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

This second edition cancels and replaces the first edition ISO 10271:2001 which has been technically revised, in particular by the inclusion of two additional test methods.

Annex A of this International Standard is for information only.

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Introduction

ISO 10271 was developed from the original Technical Report (ISO/TR 10271) as a result of worldwide demand for standard test methods to determine 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 international Standard, but it is recommended that in assessing possible biological or toxicological hazards, reference should be made to ISO 10993-1 and ISO 7405.

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 may 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 International Standard therefore gives detailed protocols for test methods which have been found to be of merit as evidenced by considerable use.

This second edition differs from the first edition by the addition of two new test methods. A time-dependence corrosion test has been added to supplement the existing static immersion test. A major reason for this test is that the corrosion rate of most dental alloys is not constant over time. Thus, the aim of the time-dependence corrosion test is to provide information on the corrosion rate of a dental alloy with time. An evaluation section to interpret the long term corrosion behaviour of the tested alloys (i.e., steady, decreasing, increasing) was not included as part of the time-dependence corrosion test. Instead, the data will be reported in a graph without attempting to interpret the shape of the resulting curve. It is intended that ISO/TC 106/SC 2/WG 12 monitor the use of the time-dependence corrosion test through the appropriate working groups in ISO/TC 106 and make any necessary changes to the document in a future revision. To supplement the sulphide tarnish test (cyclic immersion), a sulfide tarnish test (static immersion) has also been added to this second edition of ISO 10271. This test has been successfully used for many years to evaluate the corrosion of silver alloys.

In addition, an informative annex (annex A) is provided that sets out a protocol for each element of the test system such that a consistent approach may be taken for the development of further test methods. Equally, it is recognized that any element can only represent the current recommendation, but changes in the future are unlikely to change the framework

It is not the purpose of this International Standard to propose corrosion test methods for specific applications or to set limits as precise as those in the standard relating to the type of product and its application.

