SLOVENSKI STANDARD
oSIST prEN ISO 22674:2021

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Zobozdravstvo - Kovinski materiali za stalne in zamenljive zobne obnove in orodja (ISO/DIS 22674:2021)

Dentistry - Metallic materials for fixed and removable restorations and appliances (ISO/DIS 22674:2021)

Zahnheilkunde - Metallische Werkstoffe für festsitzenden und herausnehmbaren Zahnersatz und Applikationen (ISO/DIS 22674:2021)

Médecine bucco-dentaire - Matériaux métalliques pour les restaurations fixes et amovibles et les appareillages (ISO/DIS 22674:2021)

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Dentistry — Metallic materials for fixed and removable restorations and appliances

Médecine bucco-dentaire — Matériaux métalliques pour les restaurations fixes et amovibles et les appareillages

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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, *Prosthodontic materials*.

This third edition cancels and replaces the second edition (ISO 22674:2016), which has been technically revised.

The main changes compared to the previous edition are as follows:

— addition of products produced using additive and subtractive manufacturing;

— revision of definitions and addition of new definitions for modern manufacturing techniques;

— addition of overview of symbols in Clause 4 as Table 1;

— static determination of elastic modulus was added in 8.6.1.3 (as additional option);

— requirement for test report was added as Clause 9;

— harmonization of symbols in formulas.

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

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

Requirements for the performance of metals and alloys used for the metallic component of a metal-ceramic restoration contained in this document supersede such requirements formerly contained in ISO 9693. The requirements for the performance of ceramic material and the metal-ceramic bond in metal-ceramic restorative systems continue to be specified in ISO 9693.

Requirements for the proof stress and minimum elongation after fracture for Type 0 metallic materials are not included in this document, but it is recommended to adopt the test procedure given in Annex A when measuring these properties.

Dentistry — Metallic materials for fixed and removable restorations and appliances

1 Scope

This document specifies requirements and test methods for metallic materials that are suitable for the fabrication of dental restorations and appliances. Included are metallic materials recommended for use either with or without a ceramic veneer, or recommended for both uses. Furthermore, it specifies requirements with respect to packaging and marking of the products and to the instructions for use of these materials, including products delivered for sale to a third party.

This document also applies to products, which were produced using additive and subtractive manufacturing.

This document does not apply to alloys for dental amalgam (ISO 24234), dental brazing materials (ISO 9333), or metallic materials for orthodontic appliances (ISO 15841) (e.g. wires, brackets, bands and screws).

This document is not applicable to magnetic attachment, which are specified in ISO 13017.

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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 5832-2, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*

ISO 5832-3, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ISO 9513, *Metallic materials — Calibration of extensometer systems used in uniaxial testing*

ISO 9693, *Dentistry — Compatibility testing for metal-ceramic and ceramic-ceramic systems*

ISO 10271:2020, *Dentistry — Corrosion test methods for metallic materials*

ISO 12781-1, *Geometrical product specifications (GPS) — Flatness — Part 1: Vocabulary and parameters of flatness*

ISO 15223-1:2021, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
additive manufacturing
all manufacturing processes where the final object is build up layer-wise such as selective laser melting, SLM

3.2
appliance
prefabricated metallic devices such as attachments, bars

3.3
as-cast state
metallurgical condition of the *metallic material* (3.15) in its solid state when removed from the casting machine

Note 1 to entry: This condition is dependent upon the manufacturer's recommended cooling procedure (e.g. bench cooling).

3.4
base metal
any metallic element with the exception of *noble metals* (3.16) and silver

3.5
base-metal alloy
alloy having a base metal as the principal element

3.6
bench-cooling
process whereby a casting is retained in its investment with exposed metal uppermost and placed on a flat, insulating surface at ambient temperature in freely circulating air until its temperature falls to ambient

3.7
casting alloy
metallic material (3.15) designed for casting into an investment mould

3.8
ceramic veneer
thin ceramic surface layer present on a *metallic material* (3.15) restoration to provide an aesthetic effect

3.9
elastic modulus
Young's modulus
ratio of elastic stress to elastic strain

3.10
hardening
heat-treatment of a *metallic material* (3.15) producing a condition which provides a higher 0,2 % proof stress than the "as-cast" state

Note 1 to entry: If recommended by the manufacturer, explicit instructions are required in the instructions for use.

3.11
hazardous element
element that is known for its potential to produce an adverse biological effect

Note 1 to entry: The presence of such an element (as an alloying addition or as an impurity) in a dental alloy does not imply that the alloy, in itself, is hazardous.

3.12
heat treatment
any thermal treatment such as stress relieving process, softening, hardening, ceramic firings

3.13
metal-ceramic restoration
dental restoration in which a ceramic veneer is bonded to a *metallic material* (3.15) substructure by firing

Note 1 to entry: This can apply also to the *metallic material* (3.15) used for such a restoration. In this context, metal-ceramic alloy is a synonym.

Note 2 to entry: If recommended, such a *metallic material* (3.15) may be used without a ceramic veneer.

3.14
metallic base
metal with highest concentration by mass fraction in the alloy

Note 1 to entry: The name of this element shall precede the words "-based *metallic material* (3.15) for dental restoration" or "-based dental casting alloy" or "-based dental metal-ceramic material", as is appropriate.

3.15
metallic material
material having the properties that are associated with an alloy, noble metal or base metal

Note 1 to entry: This may be a pure element, commercially pure metal or an alloy.

3.16
noble metal
gold, metals of the platinum group and rhenium

3.17
one-surface inlay
inlay restoration that is exposed to the oral environment on one and no more of the surfaces that are used to define the tooth for the purposes of charting

3.18
softening
heat-treatment of a *metallic material* (3.15) producing a condition which provides a lower 0,2 % proof stress than the "as-cast" state

Note 1 to entry: If recommended by the manufacturer, explicit instructions are required in the instructions for use.

3.19
subtractive manufacturing
all manufacturing processes where a solid material such as milling blank is reduced by milling, grinding, eroding or similar techniques to the final shape

4 Symbols and classification

4.1 Symbols

Table 1 gives an overview about the symbols used in this document.

Table 1 — Symbols and their usage

Symbol	Explanation	Usage
$A_{15\ mm}$	percentage elongation after fracture	A.3.3
b	breadth	8.6.2.2 Figure 3 A.1.1, Figure A.1 B.2 Formula (B.2) C.3.2.1, C.3.2.2
C_1	correction factor 1 for the elastic modulus	Formula (2)
C_2	correction factor 2 for the shear modulus	Formula (4)
D	minimum difference between two readings that the measurement instrument can discriminate	B.1 Formula (B.1)
d	deflection	8.6.2.2
E	elastic modulus	Formula (1) Formula (B.1)
F	force	8.6.2.2
F_{60}	force required to bring the most highly stressed part of the specimen to 60 % of the material's $R_{P0,2}$	8.6.2.2
f_1	fundamental frequency measured in the flexural mode of vibration from acoustic measurement	Formula (3) B.7 B.8
f_2	fundamental frequency measured for the torsional mode of vibration	Formula (5) B.7 B.8
G	shear modulus	8.7.3 Formula (4)
h	thickness	Figure 3 8.6.2.2 Formula (2) A.1.1 Figure A.1 B.2, Formula (B.2) B.2, Formula (B.9)
h_1	greatest measured thickness	Figure 4
h_2	least measured thickness	Figure 4
L	length	Figure 3 A.1.1, Figure A.1 B.2, Formula (B.9)
L_i	inner separation of load rollers	8.6.2.1, Figure 5
L_o	outer separation of support load rollers	8.6.2.1, Figure 5
m	mass	8.6.3.2
n	number of individual readings	B.1, Formula (B.1)
q	mean of n individual readings	B.1, Formula (B.1)
q_i	value of the ith series of readings	B.1, Formula (B.1)
r	radius of the specimen	B.2, Formula (B.3)
$R_{P0,2}$	proof stress of 0,2 % non-proportional extension	8.4.1
S	cross-sectional area	7.5.2
S_0	original cross-sectional area	B.2, Formula (B.3) A.3.3

Table 1 *(continued)*

Symbol	Explanation	Usage
$u(A)$	standard uncertainty in the measurement of cross-section	B.2, Formula (B.2)
$u(b)$	standard uncertainty in the measurement of breadth of the specimen	B.2, Formula (B.2)
$u(E)$	standard uncertainty in the measurement of elastic modulus;	B.2, Formula (B.8)
$u(F)$	standard uncertainty in the measurement of load force	B.2, Formula (B.4)
$u(f)$	standard uncertainty in frequency	B.2, Formula (B.9)
$u(h)$	standard uncertainty in the measurement of thickness of the specimen	B.2, Formula (B.2)
$u(q)$	standard uncertainty in the measurement of q	B.1, Formula (B.1)
$u(r)$	standard uncertainty in the measurement of the radius of the specimen	B.2, Formula (B.3)
$u(v)$	combined standard uncertainty in the Poisson ratio	B.2, Formula (B.9)
$u(\Delta L)$	standard uncertainty in the measurements of ΔL	B.2, Formula (B.4)
x_1	gauge length of tensile specimen	Figure 1 Figure 2
x_2	parallel section of tensile specimen	Figure 1 Figure 2
v	Poisson ratio	8.6.2.2 B.2, Formula (B.9)
Δd	change in displacement of the mid-point of the specimen corresponding to the change ΔP in the load force.	B.2
ΔF	change in the force change in load force corresponding to the change in gauge length	8.6.1.2, Formula (1) B.2, Formula (B.4)
Δh	separation of outer and inner reference planes	Figure 4
ΔL_0	change in gauge length measured by the extensometer	8.6.1.2, Formula (1) B.2, Formula (B.4)

4.2 Classification

For the purposes of this document, a metallic material is classified according to its mechanical properties by a Type number, of which there are six.

Examples of the applications for which these Types are intended are as follows:

— **Type 0:** intended for low stress bearing single-tooth fixed prostheses, e.g. small veneered one-surface inlays, veneered crowns;

NOTE Metallic materials for metal-ceramic crowns produced by electroforming or sintering belong to Type 0.

— **Type 1:** for low stress bearing single-tooth fixed prostheses, e.g. veneered or unveneered one-surface inlays, veneered crowns;

— **Type 2:** for single tooth fixed prostheses, e.g. crowns or inlays without restriction on the number of surfaces;