SLOVENSKI STANDARD
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Dentistry - Duplicating material (ISO 14356:2003)

Dentistry - Duplicating material (ISO 14356:2003)

Zahnheilkunde - Dubliermassen

Art dentaire - Produits pour duplication (ISO 14356:2003)

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Art dentaire - Produits pour duplication (ISO 14356:2003)

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This European Standard was approved by CEN on 21 February 2003.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 14356:2003) 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of an identical text or by endorsement, at the latest by September 2003, and conflicting national standards shall be withdrawn at the latest by September 2003.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 14356:2003 has been approved by CEN as EN ISO 14356:2003 without any modifications.

NOTE Normative references to International Standards are listed in annex ZA (normative).

Annex ZA
(normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 1942-1	1989	Dental vocabulary - Part 1: General and clinical terms	EN 21942-1	1991
ISO 1942-2	1989	Dental vocabulary - Part 2: Dental materials	EN 21942-2	1992
ISO 1942-3	1989	Dental vocabulary - Part 3: Dental instrument	EN 21942-3	1993
ISO 1942-4	1989	Dental vocabulary - Part 4: Dental equipment	EN 21942-4	1993
ISO 1942-5	1989	Dental vocabulary - Part 5: Terms associated with testing	EN ISO 1942-5	1994
ISO 6873	1998	Dental gypsum products	EN ISO 6873	2000
ISO 7490	2000	Dental gypsum-bonded casting investments	EN ISO 7490	2000
ISO 9694	1996	Dental phosphate-bonded casting investments	EN ISO 9694	1998
ISO 11245	1999	Dental restorations - Phosphate-bonded refractory die materials	EN ISO 11245	2000
ISO 11246	1996	Dental ethyl silicate-bonded casting investments	EN ISO 11246	1998

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14356 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

Dentistry — Duplicating material

1 Scope

This International Standard specifies requirements and tests for the duplicating materials used in dentistry which are primarily intended for forming flexible moulds needed to produce positive refractory investment copies of properly blocked-out master models.

2 Normative references

The following referenced documents are indispensable for the application 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 (all parts), *Dental vocabulary*

ISO 6873, *Dental gypsum products*

ISO 7490, *Dental gypsum-bonded casting investments*

ISO 9694, *Dental phosphate-bonded casting investments*

ISO 11245, *Dental restorations — Phosphate-bonded refractory die materials*

ISO 11246, *Dental ethyl silicate bonded casting investments*

3 Terms and definitions

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

3.1
block out
to flow or mould waxes and/or materials such as cements, clays and polymeric materials into undercut areas on a master model, and then shape them so as to leave only those undercuts that are essential to the subsequent steps in producing a prosthesis that will fit and function optimally

NOTE A blocked-out master model may also include other surface modifications needed relative to construction of a prosthesis.

3.2
double boiler
container system, usually in three parts, in which the upper container fits into the lower container such that boiling water in the lower container heats the contents of the lid-covered upper container

3.3
duplicating material
elastic material used to make flexible negative copy impressions or moulds of objects (models or casts) into which a mix of a refractory investment, or another mixture intended for a similar purpose, can be poured to produce a positive copy of the original object

3.4
non-reversible duplicating material
material which converts from a pourable consistency to a gel or rubber-like state and which thereafter cannot be returned to the pourable consistency for repeated use

3.5
reversible duplicating material
material which can be recycled for more than one use by changing it, by means of heating, from an elastic gel state to a pourable consistency, and then returning it to the gel state by cooling

3.6
duplicating process
⟨for making metal and ceramic objects⟩ method for making positive copies of master models from a negative mould

NOTE 1 The process is carried out according to the following steps:

— master model is blocked out,

— duplicating material is poured around blocked-out master model and allowed to gel or set,

— master model is separated from the duplicating material, leaving a flexible mould having surfaces that constitute a negative copy of the surfaces of the master model,

— an investment mixture is poured into the mould to form a refractory model on which polymeric or wax patterns, or both, can be laid down to form the shapes desired in metal or ceramic castings or on which slurries of porcelain can be applied for forming desired shapes.

NOTE 2 Gypsum product mixtures or other mixtures may be poured into the moulds to form copies of master models needed for other purposes.

3.7
effective setting time
⟨for materials setting at or near oral or room temperature⟩ time measured from the commencement of mixing components of a material together, or otherwise activating the chemistry involved, to the time at which the activated material has developed the properties (elasticity, hardness, etc.) that will permit it to be used with optimal effectiveness in a subsequent step or for its intended purpose

3.8
functional life
⟨reversible duplicating material⟩ number of times a material can be recycled for use, if handled and used according to the manufacturer's instructions, without loss of the properties required to ensure that the material is fit for the purpose intended

3.9
gelation
⟨agar duplicating material⟩ transition of a material from a relatively fluid consistency to a gel state in which the material has developed the elastic properties needed for its intended purpose

3.10
immediate container
packaging component having internal surfaces in direct contact with the material contained

NOTE An immediate container may be a unlabelled container protected by more durable outer packaging, such as a can, carton or drum. If strong enough to protect its contents without outer packaging, an immediate container can serve as a primary container on which labelling may be required.

3.11
initial setting time
time measured from the commencement of mixing components of a material together, or otherwise activating the chemistry involved, to the time at which a test procedure, conducted at a specified temperature, indicates that the mixture has begun to set at a relatively rapid rate, thus indicating that the effective setting time will be reached at some predictable time thereafter

NOTE Initial setting times stated in the manufacturer's instructions are useful to test operators, users, and standards developers because:

— they can often be used for determining whether a product is of a quality suitable for testing or use. For example, if the initial setting time found by the test operator or user corresponds closely to that stated in the instructions, it can usually be assumed that the product is suitable for testing or use.

— they can be helpful in the development of standards for certain materials if there is a need for a standard to identify a reference point in time that can be used as a basis for specifying when certain subsequent procedures should begin.

3.12
investment
⟨casting⟩ powdered refractory material containing a binder, to be mixed with a specified liquid to form a slurry that can be poured into a mould made of duplicating material where it is allowed to harden to form a heat-resistant positive copy of a master model, or which can be poured around patterns to form a heat-resistant mould used for forming ceramic or metal objects

3.13
master model
definitive cast

⟨fixed and removable denture construction⟩ positive copy of the hard and/or soft tissues of a dental arch, usually made by pouring a gypsum product slurry into an impression made of a dental arch

3.14
melt
⟨agar reversible duplicating material⟩ change a material, by heating, from a gel state to a pourable fluid state

3.15
outer package
wrapping or carton which is used to cover one or more immediate or primary containers in preparation for retail marketing and which may be required by law or International Standard to bear specified labelling information

3.16
pouring temperature
⟨duplicating material⟩ temperature of the material designated in the manufacturer's instructions for pouring the material around an object to be duplicated

3.17
primary container
retail marketing packaging component which may or may not be covered by an outer package and which may be required by law or International Standard to bear specified labelling information

EXAMPLE Bottle, carton, drum, jar, or tube, etc.

NOTE A primary container may also be an immediate container, and vice versa.