SLOVENSKI STANDARD
SIST EN ISO 4823:2015

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SIST EN ISO 4823:2001
SIST EN ISO 4823:2001/A1:2008
SIST EN ISO 4823:2001/AC:2006

Zobozdravstvo - Elastomerni materiali za odtise (ISO 4823:2015)

Dentistry - Elastomeric impression materials (ISO 4823:2015)

Zahnheilkunde - Elastomere Abformmaterialien (ISO 4823:2015)

Médecine bucco-dentaire - Produits pour empreintes, à base d'élastomères (ISO 4823:2015)

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11.060.10	Zobotehnični materiali	Dental materials

SIST EN ISO 4823:2015 **en**

EUROPEAN STANDARD

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EN ISO 4823

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English Version

Dentistry - Elastomeric impression materials (ISO 4823:2015)

Médecine bucco-dentaire - Matériaux à empreintes, à base d'élastomères (ISO 4823:2015)

Zahnheilkunde - Elastomere Abformmaterialien (ISO 4823:2015)

This European Standard was approved by CEN on 20 June 2015.

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

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European foreword

This document (EN ISO 4823:2015) 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of an identical text or by endorsement, at the latest by February 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 4823:2000.

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Endorsement notice

The text of ISO 4823:2015 has been approved by CEN as EN ISO 4823:2015 without any modification.

INTERNATIONAL STANDARD

ISO 4823

Fourth edition
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Dentistry — Elastomeric impression materials

Médecine bucco-dentaire — Matériaux à empreintes, à base d'élastomères

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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).

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This fourth edition cancels and replaces the third edition (ISO 4823:2000), which has been technically revised with the following changes:

— modification of the sequence of requirements having the requirements for packaging and labelling listed before the requirements for characteristics and properties;

— the restriction that the working time shall be at least 30 s longer than the mixing time was eliminated; this was considered necessary in view of the fact that several products have shorter working time;

— working time test procedure using the dead weight method (Sink-in method) for Type 0 materials which had been exempt from this requirement in the third edition was introduced (see 7.3.2);

— the current displacement Rheometer procedure stated in ISO 4823:2000 will continue to be used for testing Type 1, 2, and 3 materials without modifications;

— concerning the order in which some clauses are presented, whereas in later years, most dental product standards have been structured to have the requirements and test methods clauses appear before the requirements for labelling and instructions for use clauses, this International Standard gives first ordering to the labelling and instructions for use requirements. This change was thought to be necessary because experience informs us that test operators will be better equipped to obtain success in testing if they first take into account the information available in the labelling and in the instructions for use;

— Clause 6 has been added for reasons explained in its first paragraph;

— concerning the Annexes

  — Annex A was created due to the ISO Central Secretariat suggestion that all figures, grouped together instead of being presented individually on related pages of the text, are to be presented in a normative Annex and numbered according to existing rules. This is to make it easier for the figures to be located by users of the document;

— Annex B provides for standardized hand mixing methods to be used by test operators so that specimen preparation mixing of the test specimens will be uniform and consistently fairer to the various products;

— Annex C identifies sources for the working-time test apparatus and the linear variable displacement transducer (LVTD).

Dentistry — Elastomeric impression materials

1 Scope

This International Standard specifies the requirements and tests that the state-of-the art body of knowledge suggests for helping determine whether the elastomeric impression materials, as prepared for retail marketing, are of the quality needed for their intended purposes.

NOTE This International Standard does not address possible biological hazards associated with the materials. Therefore, interested parties are encouraged to explore ISO 7405 and ISO 10993 for assessment of such hazards.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 6873, *Dentistry — Gypsum products*

3 Terms and definitions

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

3.1
consistency
degree of firmness with which particles of a material, prepared for use, cohere so as to allow the material to flow, or resist flow, as required to achieve the purpose for which it is intended

3.2
elastic recovery test
DEPRECATED: compression set
DEPRECATED: permanent deformation
DEPRECATED: recovery from deformation
⟨elastic impression materials⟩ method of determining whether the materials possess the elastic properties required to recover adequately after deformation occurring when the materials used for forming impressions are removed from the mouth

3.3
extrusion mixing
method by which two or more material components are extruded simultaneously from their separate primary containers through a special mixing tip from which the material components emerge as a homogeneous mixture

3.4
hand mixing
method of mixing the components of a material by means of manual kneading or spatulation

3.5
primary packaging
container designed to come into direct contact with the product

[SOURCE: ISO 21067:2007, 2.2.2, modified — “packaging” replaced by “container” in the definition.]

3.6
mixing time
time, measured from first contact between different components of a material being mixed, required to achieve a homogeneous mixture when the components are mixed according to the manufacturer's instructions

Note 1 to entry: The time of first contact between extrusion-mixed material components is defined as the time when the material components can be seen entering into the mixing nozzle.

3.7
outer package
wrapping or carton, which may be required by law or a standard to bear specified labelling, used to cover one or more primary containers in preparation for retail marketing

3.8
strain-in-compression test
⟨elastic impression materials⟩ method of measuring the flexibility/stiffness property ranges of materials so as to determine whether the set materials, when formed as impressions, can be removed from the mouth without injury to impressed oral tissues and will have adequate stiffness in the more flexible portions of impressions to resist deformation when model-forming products are poured against them

3.9
working time
period of time beginning with the commencement of mixing and ending before the material being mixed has begun to exhibit elastic properties that will prevent the material from being manipulated as required to form an impression or a mould having the desired surface detail and dimensional characteristics

4 Classification

Materials covered by this International Standard are classified according to the following consistencies determined immediately after completion of mixing according to the manufacturer's instructions (see 5.3):

— Type 0: putty consistency;

— Type 1: heavy-bodied consistency;

— Type 2: medium-bodied consistency;

— Type 3: light-bodied consistency.

5 Requirements for packaging, labelling, and information in manufacturer's instructions

5.1 Packaging requirements

No packaging requirements are specified in this International Standard, but it is important for manufacturers to take into account that the packaging should be such that it will not contaminate or permit contamination of ingredients of the material components during recommended storage conditions. Structure of the primary packaging should also be such that no leakage or inadvertent extrusion of the contents can occur during storage and such that the containers will not rupture during use of the extrusion methods recommended by the manufacturer.

5.2 Labelling requirements

5.2.1 Outer packages (containing one or more primary containers)

Labelling of the outer packaging prepared for retail marketing containing one or more primary containers shall bear the following information:

a) recommended storage conditions for the unopened package;

b) brand name;

c) name and address of the manufacturer or the name of another company authorized by the manufacturer to market the material under a different brand name;

d) identification of the consistency of the material as putty, heavy-bodied, medium-bodied, or light-bodied (see Clause 4) (the type number may also be included);

e) manufacturer's batch reference(s);

f) USE BEFORE DATE, identified as such, beyond which the material may not exhibit its best properties. The date shall be expressed as a six-digit number, for example, 2014-09, where the first four digits indicate the year (2014) and the last two digits indicate the month (September);

g) minimum volume that would result from mixing the entire component contents included in the outer package.

5.2.2 Primary containers within outer packaging

Labels for primary containers shall bear the following information:

a) brand name;

b) name of the manufacturer or name of another company authorized to market the material under a different brand name;

c) component identification (not required when the components for extrusion mixing are supplied in separate but joined primary containers);

d) manufacturer's batch references.

5.3 Requirements for information in manufacturer's instructions

5.3.1 General

Each package in which the components of an impression material are prepared for retail marketing shall be accompanied by the instructions and other information needed to ensure optimum performance of the material in clinical practice

5.3.2 Identifying information

The following identifying information is required:

a) trade-name or brand-name of the product;

b) chemical nature of the elastomeric system: for example, polyether, polysulfide, silicone (condensation type), or silicone (vinyl polysiloxane, addition type).