



SLOVENSKI STANDARD

oSIST prEN ISO 4823:2020

01-julij-2020

Zobozdravstvo - Elastomerni materiali za odtise in ugriz (ISO/DIS 4823:2020)

Dentistry - Elastomeric impression and bite registration materials (ISO/DIS 4823:2020)

Zahnheilkunde - Elastomere Abformmaterialien und Bissregistriermassen (ISO/DIS 4823:2020)

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Dentistry — Elastomeric impression and bite registration materials

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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, *Prosthetic materials*.

This fifth edition ~~cancels and replaces the fourth edition (ISO 4823:2015)~~, which has been technically revised and enhanced with regard to elastomeric bite registration materials. The following changes have been applied:

- title and scope changed to reflect inclusion of elastomeric bite registration materials;
- added ISO 48-4:2018 as a normative reference;
- added description of minimum time in the oral cavity for bite registration materials;
- added description of hardness of bite registration materials.

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Dentistry — Elastomeric impression and bite registration materials

1 Scope

This document specifies the requirements and their test methods for elastomeric impression and bite registration materials.

NOTE This document 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 are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 48-4:2018, *Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by durometer method (Shore hardness)*

ISO 1942, *Dentistry — Vocabulary*

ISO 6873:2013, *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.

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

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

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

3.2

elastic recovery

<elastic impression materials> elastic properties required to recover adequately after deformation

3.3

extrusion mixing

method by which two or more material components are extruded simultaneously from their separate primary containers through a mixing nozzle 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

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3.5

hardness

Shore hardness according to ISO 48-4:2018 Type A

3.6

minimum time in the oral cavity

minimum time span the material has to stay in the oral cavity before removal to sufficiently minimize deformation

3.7

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.

3.8

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

3.9

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.]

3.10

strain in compression

elastic impression materials) / 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

3.11

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;
- Type B: bite registration materials.

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

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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).

5.3.3 Specific instructions for use

Where applicable, the specific instructions for use shall include the following:

- a) recommended storage conditions after the initial opening of the primary containers;
- b) statements indicating that working time and other characteristics of the material can be affected significantly by the following factors, as may be applicable:
 - room temperature variations;
 - variations in the speed and friction involved in mixing;
 - hand/fingertip temperatures when kneading putty mixes;
 - moisture contamination or relative humidity;
 - contamination, either due to direct contact with latex dam or gloves used in clinical practice or due to the presence of such contaminants on teeth at the time they are impressed;
- c) proportions for hand-spatulated mixes (mass to mass and volume to volume);
- d) recommended mixing apparatus and procedures to include the generic identification of any hand coverings (gloves or polymer sheeting) that should be used to avoid contamination of the materials during hand manipulation;
- e) mixing time required to obtain a homogeneous mixture of an amount of the material having a volume of 15 ml (see 5.3.3. d and Annex B);
- f) working time;
- g) minimum time the material should remain in the mouth before removal; The following items only apply to impression materials:
- h) minimum or maximum time lapse, or both, permitted between removal of the impression from the mouth and pouring the gypsum product into the impression;
- i) identification of at least two gypsum products, complying with requirements of ISO 6873:2013, which the impression material manufacturer has found to be compatible with the impression material being tested: one Type 3 product (dental stone, model) and either one Type 4 product or one Type 5 product (dental stone, high strength);
- j) when the manufacturer's instructions state that an impression made of a material may be disinfected, the disinfecting procedure shall be described in detail and a reference indicating that the disinfection procedure will not alter the potential of the impression for optimum performance shall also be identified;
- k) when a manufacturer claims that a material in itself is antimicrobial and will remain so without further treatment after the impression is removed from the mouth, the manufacturer shall identify the reference on which the claim is based.

5.4 Requirements for characteristics and properties

5.4.1 Component colours (hand-spatulated or hand-kneaded mixes)

Different components intended for use in the same mixture shall be supplied in contrasting colours to provide a means of determining when the components have been thoroughly mixed.

5.4.2 Mixing time (hand-spatulated or hand-kneaded mixes)

When the material components are combined according to the manufacturer's instructions and the results of the mixing are evaluated according to 7.1, the average time required to achieve a homogeneous mixture (essentially streak-free) shall not exceed the time stated by the manufacturer.

5.4.3 Consistency

When tested according to 7.2, the test disc diameter shall be in the range given in Table 1 for the consistency assigned to the material by the manufacturer.

5.4.4 Working time

When tested according to 7.3, the working time shall not be less than that stated in the manufacturer's instructions.

5.4.5 Detail reproduction

When tested according to 7.4, the line width reproduced shall not exceed the appropriate value given in Table 1.

5.4.6 Linear dimensional change

When tested according to 7.5, the linear dimensional change shall not exceed the appropriate value given in Table 1.

5.4.7 Compatibility with gypsum

The impression material shall impart a smooth surface to and separate cleanly from the gypsum model material poured against it. When tested according to 7.6, the line width reproduced shall not exceed the appropriate value given in Table 1.

5.4.8 Elastic recovery

When tested according to 7.7, the elastic recovery shall be greater than or equal to the value given in Table 1.

5.4.9 Strain-in-compression

When tested according to 7.8, the strain-in-compression shall be in the appropriate range given in Table 1.

5.4.10 Minimum time in the oral cavity for bite registration materials

When tested according to 7.9, the minimum time in the oral cavity shall be smaller than or equal to the value given by the manufacturer in the instructions for use.

5.4.11 Compression set of bite registration materials

When tested according to 7.9, the compression set after load removal shall be less or equal to the value given in Table 1.