Dentistry - Elastomeric impression materials (ISO 4823:2015)

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 4823:2015 sisaldab Euroopa standardi EN ISO 4823:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 4823:2015 consists of the English text of the European standard EN ISO 4823:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 12.08.2015.	Date of Availability of the European standard is 12.08.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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of an identical text or by endorsement, at the latest by February 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

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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.

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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.]