

Dentistry - Elastomeric impression and bite registration materials (ISO 4823:2021)

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EUROPEAN STANDARD

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Dentistry - Elastomeric impression and bite registration materials (ISO 4823:2021)

Médecine bucco-dentaire - Produits pour empreintes et matériaux pour enregistrement des rapports intermaxillaires à base d'élastomères (ISO 4823:2021)

Zahnheilkunde - Elastomere Abformmaterialien und Bissregistriermassen (ISO 4823:2021)

This European Standard was approved by CEN on 17 March 2021.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 4823:2021) 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of an identical text or by endorsement, at the latest by September 2021, and conflicting national standards shall be withdrawn at the latest by September 2021.

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

This document supersedes EN ISO 4823:2015.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 4823:2021 has been approved by CEN as EN ISO 4823:2021 without any modification.

Contents

	Page
Foreword.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Classification.....	2
5 Requirements.....	3
5.1 Packaging requirements.....	3
5.2 Labelling requirements.....	3
5.2.1 Outer packages (containing one or more primary containers).....	3
5.2.2 Primary containers within outer packaging.....	3
5.3 Requirements for information in the manufacturer's instructions.....	4
5.3.1 General.....	4
5.3.2 Identifying information.....	4
5.3.3 Specific instructions for use.....	4
5.4 Requirements for characteristics and properties.....	5
5.4.1 Component colours (hand-spatulated or hand-kneaded mixes).....	5
5.4.2 Mixing time (hand-spatulated or hand-kneaded mixes).....	5
5.4.3 Consistency.....	5
5.4.4 Working time.....	5
5.4.5 Detail reproduction.....	5
5.4.6 Linear dimensional change.....	5
5.4.7 Compatibility with gypsum.....	5
5.4.8 Elastic recovery.....	5
5.4.9 Strain in compression.....	5
5.4.10 Minimum time in the oral cavity for bite registration materials.....	6
5.4.11 Compression set of bite registration materials.....	6
5.4.12 Hardness of bite registration materials.....	6
6 Pre-test planning approaches.....	6
6.1 Sampling.....	6
6.2 Pre-test product examinations.....	7
6.2.1 Examinations for compliance with labelling requirements.....	7
6.2.2 Examinations for effectiveness of the packaging.....	7
6.2.3 Examinations for compliance with requirements for instructions for use.....	7
6.3 Essential pre-test preparatory practices.....	7
6.3.1 Laboratory conditions.....	7
6.3.2 Apparatus function verification steps.....	8
6.3.3 Volume of materials to be mixed for each specimen.....	8
6.3.4 Standardized approaches to proportioning, mixing, and handling of hand mixed materials to be tested.....	8
6.3.5 Timing for the specimen preparation and test procedures.....	8
6.3.6 Simulated oral time/temperature treatment of specimens formed in completely closed mould assemblies.....	8
6.4 Pass/fail determinations.....	8
6.5 Expression of test results.....	8
7 Test methods — Specific.....	8
7.1 Mixing time.....	8
7.1.1 Apparatus.....	8
7.1.2 Specimen preparation and test procedure (five specimens).....	9
7.1.3 Pass/fail determination and expression of results.....	9
7.2 Consistency.....	9
7.2.1 Apparatus and materials.....	9
7.2.2 Advance preparation steps.....	9

7.2.3	Specimen preparation and test procedure (5 specimens)	10
7.2.4	Pass/fail determination and expression of results	10
7.3	Working-time	10
7.3.1	Apparatus	10
7.3.2	Working time test	11
7.4	Detail reproduction	12
7.4.1	Apparatus and materials	12
7.4.2	Specimen preparation	12
7.4.3	Test procedure	13
7.4.4	Pass/fail determination and expression of results	13
7.5	Linear dimensional change	13
7.5.1	Apparatus and materials	13
7.5.2	Test block line-length measurement procedure	14
7.5.3	Specimen preparation	14
7.5.4	Test specimen measurement	14
7.6	Compatibility with gypsum	15
7.6.1	Apparatus and materials	15
7.6.2	Specimen preparation	16
7.6.3	Test procedure	16
7.6.4	Pass/fail determination and expression of results	16
7.7	Elastic recovery	17
7.7.1	Apparatus and materials	17
7.7.2	Specimen preparation	17
7.7.3	Test procedure	18
7.7.4	Calculation of results	18
7.7.5	Pass/fail determination and expression of results	18
7.8	Strain in compression	18
7.8.1	Apparatus	18
7.8.2	Specimen preparation	19
7.8.3	Test procedure	19
7.8.4	Calculation of results	19
7.8.5	Pass/fail determination and expression of results	19
7.9	Minimum time in the oral cavity and compression set for bite registration materials	19
7.9.1	Apparatus	19
7.9.2	Specimen preparation	19
7.9.3	Test procedure	19
7.9.4	Evaluation	20
7.9.5	Pass/fail determination and expression of results	20
7.10	Hardness of bite registration materials	20
7.10.1	Apparatus	20
7.10.2	Specimen preparation	20
7.10.3	Test procedure	20
7.10.4	Evaluation	21
7.10.5	Pass/fail determination and expression of results	21
Annex A (normative) Figures		22
Annex B (normative) Standardized hand mixing methods		30
Bibliography		33

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/ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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:

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

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.

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. Assessment of these hazards is addressed in ISO 7405 and the ISO 10993 series.

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 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 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