SLOVENSKI STANDARD
SIST EN ISO 4823:2001

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SIST EN 24823:2000

Dentistry - Elastomeric impression materials (ISO 4823:2000)

Dentistry - Elastomeric impression materials (ISO 4823:2000)

Zahnheilkunde - Elastomere Abformmassen (ISO 4823:2000)

Art dentaire - Produits pour empreintes, a base d'élastomeres (ISO 4823:2000)

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Dentistry - Elastomeric impression materials (ISO 4823:2000)

Art dentaire - Produits pour empreintes, à base d'élastomères (ISO 4823:2000)

Zahnheilkunde - Elastomere Abformmassen (ISO 4823:2000)

This European Standard was approved by CEN on 15 December 2000.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard ISO 4823:2000 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 supersedes EN 24823:1993.

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of an identical text or by endorsement, at the latest by June 2001, and conflicting national standards shall be withdrawn at the latest by June 2001.

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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 4823:2000 was approved by CEN as a European Standard without any modification.

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

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normativereferences 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/HD	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 instruments	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

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 4823 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This third edition cancels and replaces the second edition (ISO 4823:1992), which has been revised to reflect the following technical differences:

— the 60 s limit on **Mixing time** (5.4, second edition) has been eliminated;

— the **Consistency test** requirement for **Type 1** and **Type 2** impression materials has been relaxed (see Table 1, both editions);

— a more realistic approach for making pass/fail determinations (8.4);

— apparatus and procedures specified for the **Working-time test** (9.3) and the **Elastic recovery tests** (9.7) provide for more objective test results than those specified in 7.4 and 7.6 of the second edition;

— Figure 2 illustrates how the instrument depicted in Figure 4 of the second edition can be modified to make it suitable for use in the **Consistency test** as well as for the **Strain-in-compression test**;

— Figure 15 illustrates how the **split mould** shown in Figure 5 of the second edition can be modified to provide for more uniformly shaped specimens.

Annex A of this International Standard is for information only.

Dentistry — Elastomeric impression materials

1 Scope

This International Standard specifies requirements and tests for evaluating elastomeric dental impression materials.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1942, *Dental vocabulary.*

ISO 6873, *Dental gypsum products.*

3 Terms and definitions

For the purposes of this International Standard, 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
compression set (deprecated)
permanent deformation (deprecated)
recovery from deformation (deprecated)
⟨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 from their separate immediate containers through a special mixing tip, from which the 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
immediate container
container which is in direct contact with a material or a component thereof

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

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 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 immediate or primary containers in preparation for retail marketing

3.8
primary container
retail marketing packaging component, such as a bottle, carton, drum, jar, tube, etc., which may be required by law or a standard to bear specified labelling

NOTE A primary container may also be an immediate container.

3.9
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, 1) can be removed from the mouth without injury to impressed oral tissues, and 2) will have adequate stiffness, in the more flexible portions of impressions, to resist deformation when model-forming products are poured against them

3.10
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 consistencies determined immediately after completion of mixing according to the manufacturer's instructions (10.3):

— Type 0: putty consistency

— Type 1: heavy-bodied consistency

— Type 2: medium-bodied consistency

— Type 3: light-bodied consistency

5 Biocompatibility advisory

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard. It is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 7405 and ISO 10993-1 (see Bibliography).

6 Requirements for characteristics and properties

6.1 Component colours

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.

6.2 **Mixing time** (hand-spatulated or hand-kneaded mixes)

When the impression material components are combined according to the manufacturer's instructions given in 10.3 e) and the results of the mixing are evaluated according to 9.1, the average time required to achieve a homogeneous mixture (essentially streak free) shall not exceed the time stated by the manufacturer in 10.3 e).

6.3 Working time

When tested according to 9.3, the working time shall not be less than that stated in the manufacturer's instructions given in 10.3 f), and shall be at least 30 s longer than the time required to obtain a homogeneous mix (see 6.2 and 9.1).

6.4 Compatibility with gypsum

The impression material shall impart a smooth surface to, and separate cleanly from, the gypsum model material poured against it (see Table 1).

Table 1 — Additional characteristic and physical property requirements

Type	Test subclause No. and description							
	9.2		9.4	9.5	9.6	9.7	9.8	
	Consistency (Test disc diameter) mm		Detail reproduction (Line width reproduced) [a]	Linear dimensional change	Compatibility with gypsum (Line width reproduced) [a]	Elastic recovery	Strain-in-compression	
	min.	max.	µm	% max.	µm	% min.	% min.	% max.
0	—	35	75	1,5	75	96,5	0,8	20
1	—	35	50	1,5	50	96,5	0,8	20
2	31	41	20	1,5	50	96,5	2,0	20
3	36	—	20	1,5	50	96,5	2,0	20

[a] The line reproduction shall be considered satisfactory if the required line a, b, or c is continuous between the lines d_1 and d_2. See test block in Figure 12.

NOTE Requirements for information to be included in the manufacturer's instructions for use, packaging and labelling are listed in clauses 10 and 11.