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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the 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)

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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of an identical text or by endorsement, at the latest by September 2021, and conflicting national standards shall be withdrawn at the latest by September 2021.

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Dentistry — Elastomeric impression and bite registration materials

*Médecine bucco-dentaire — Produits pour empreintes et matériaux
pour enregistrement des rapports intermaxillaires à base
d'élastomères*



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ISO 4823:2021(E)

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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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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*

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