INTERNATIONAL STANDARD

**ISO 4823**

Fourth edition
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# Dentistry — Elastomeric impression materials

*Médecine bucco-dentaire — Matériaux à empreintes, à base d'élastomères*

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# Foreword

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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 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).