INTERNATIONAL STANDARD

**ISO 21563**

First edition
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# Dentistry — Hydrocolloid impression materials

*Médecine bucco-dentaire — Produits pour empreintes à base d'hydrocolloïdes*



Reference number
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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 21563 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This first edition of ISO 21563 constitutes a consolidation of the three standards listed below and, as such, cancels and replaces, in whole, all three of the standards listed.

— ISO 1563:1990, *Dentistry — Alginate impression materials*

— ISO 1564:1995, *Dental aqueous impression materials based on agar*

— ISO 13716:1999, *Dentistry — Reversible/irreversible hydrocolloid impression materials systems*

Re-evaluations of all the provisions stated in the three ISO standards to be included in the consolidation led to the significant technical changes listed as follows.

— The alginate hydrocolloid impression materials (ISO 1563) are now required to be subject to the same tear strength test that has been in effect for the agar hydrocolloid impression materials (ISO 1564 and ISO 13716) instead of being subject to a compressive strength test.

— The requirement for the alginate impression material powder materials to be “free from foreign materials”, as stated in ISO 1563, has not been carried forward into the consolidation because no objective test has been specified for determining compliance with the requirement.

— The “gelation temperature” requirements in ISO 1564 and ISO 13716 have not been carried forward for the agar impression materials because results of the elastic recovery test (7.5), if conducted following the required manufacturer’s instructions for use (8.2.1 and/or 8.2.2), will indicate whether adequate gelation will take place during clinical use of the materials.



 

# Introduction

Parties seeking clarification of any provisions of this International Standard, or desiring to recommend improvements for the next edition, are encouraged to do so by contacting ISO/TC 106, Dentistry, whose address can be obtained through inquiry to the national standards body representing the interests of the inquiring parties.

# Dentistry — Hydrocolloid impression materials

## 1 Scope

This International Standard specifies the requirements and tests for helping determine whether the elastic aqueous agar and alginate hydrocolloid dental impression materials, as prepared for retail marketing, are of the quality needed for their intended purposes. It also specifies requirements for labelling and instructions for use.

NOTE This International Standard specifies no requirements or tests for freedom from unacceptable biological hazards. However, it is recommended that, to address possible biological hazards associated with the use of hydrocolloid impression materials, interested parties should refer to ISO 7405 and ISO 10993.

## 2 Normative references

The following referenced documents are indispensable for application 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 1942, *Dentistry — Vocabulary*

ISO 6873, *Dentistry — Gypsum products*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

**3.1**
**bonding**
adherence of the reversible and non-reversible impression material components constituting a single impression after each of the separate but interfacing materials has reached the level of elasticity and effective setting required for successful removal from the mouth

**3.2**
**bulk container**
labelled consumer packaging or primary packaging container holding a greater amount of otherwise unpackaged granular, liquid, powder, or other loose substance than is usually needed for a single dental clinical or laboratory procedure

**3.3**
**combined reversible/non-reversible impression material system**
system of impression making in which a light bodied agar material is first syringed around selected teeth so that it can bond with the non-reversible alginate material that will be forced over it later during the formation of an impression

**3.4**
**consumer packaging**
retail packaging
sales packaging
packaging constituting, with its contents, a sales unit to the final user or consumer at the point of retail

[SOURCE: ISO 21067:2007, definition 2.2.5]