

Dental elastic impression material —

Part 2: Specification for alginate impression material

The European Standard EN 21563:1991 has the status of a
British Standard

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/51, upon which the following bodies were represented:

- Association of Dental Hospitals of the United Kingdom
- British Ceramic Research Ltd.
- British Dental Association
- British Dental Trade Association
- British Institute of Surgical Technologists
- British Society for the Study of Orthodontics
- British Society for the Study of Prosthetic Dentistry
- Dental Laboratories Association Limited
- Department of Conservative Dentistry
- Department of Health
- General Dental Practitioners' Association
- Ministry of Defence
- Orthodontic Technicians' Association
- Society of University Dental Instructors

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 28 June 1991

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National foreword

This revision of BS 4269-2 has been prepared under the direction of the Health Care Standards Policy Committee and supersedes BS 4269-2:1980 which is withdrawn. It is identical with ISO 1563:1990 “*Dental alginate impression material*”, prepared by Technical Committee 106, Dentistry, of the International Organization for Standardization (ISO), with the active participation of the UK. In 1991 the European Committee for Standardization (CEN) accepted ISO 1563:1990 as European Standard EN 21563:1991.

ISO 1563:1991 differs from the previous edition in the following respects.

- a) The system of classification into classes A, B and C based on clinical application has been deleted because it has been recognized that class A alginate materials should not be used to obtain models for making fixed restorations and that all class C alginates can be used for normal impression procedures. As a consequence the viscosity requirement has also been deleted. The system of classification into types I and II, based on the speed of setting, has also been deleted because it has been recognized that the best indication of the speed of setting is given by the setting time itself.
- b) The test for setting time given in the first edition of ISO 1563 has been omitted because it proved to be too laborious and because no other test has been introduced due to lack of knowledge about the clinical significance. As a result this revision does not contain a requirement for the setting time as such but requires the manufacturer’s stated setting time to be checked by the requirement on recovery after deformation.
- c) The water-bath testing temperature is now defined as $35 \pm 1\text{ }^{\circ}\text{C}$, the temperature which offers a heating rate of the test specimen comparable to the heating rate of impression material under oral conditions.
- d) The requirement as to the proportioning devices has been deleted because of the opinion that a moderate deviation in the powder-to-water ratio will not affect clinical results.

The introduction to ISO 1563 reads as follows.

“While it was recognized by the committee that prepared this International Standard that the mixed paste, when used in accordance with the manufacturer’s instructions, should have no unpleasant odour or flavour, the committee was unable to specify any requirements in this respect. The material should neither cause irritation of the normal oral mucosa nor contain poisonous ingredients of sufficient quantity to harm human beings. Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that reference should be made ISO/TR 7405, *Biological evaluation of dental materials*, when assessing possible biological or toxicological hazards.”

Cross-reference

International Standard	Corresponding British Standard
ISO 6873:1983	BS 7013:1989 <i>Specification for dental gypsum products</i> (Identical)

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 12, an inside back cover and a back cover. This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

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Descriptors: Dentistry, dental materials, dental impressions, alginates, characteristics, tests, marking, labelling

English version

Alginate dental impression material

(ISO 1563:1990)

Produits pour empreintes dentaires à base
d'alginate
(ISO 1563:1990)

Zahnärztliche Alginat-Abformmasse
(ISO 1563:1990)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

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Foreword

This European Standard has been taken over by CEN/TC 55 “Dental products” from the work of ISO/TC 106 “Dentistry” of the International Organization for Standardization (ISO).

CEN/TC 55 decided to submit this final draft to the CEN Members for voting by Unique Acceptance Procedure (UAP). The standard was approved.

National standards identical to this European Standard shall be published at the latest by 92-05-06 and conflicting national standards shall be withdrawn at the latest 92-05-06.

In accordance with the Common CEN/CENELEC Rules the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.