SLOVENSKI STANDARD
SIST EN 21563:2000

01-januar-2000

Alginate dental impression material (ISO 1563:1990)

Alginate dental impression material (ISO 1563:1990)

Zahnärztliche Alginat-Abformmasse (ISO 1563:1990)

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

Ta slovenski standard je istoveten z: **EN 21563:1991**

ICS:

11.060.10 Zobotehniļ ni materiali Dental materials

SIST EN 21563:2000 **en**

EUROPEAN STANDARD

NORME EUROPEENNE

EUROPAISCHE NORM

EN 21563:1991

November 1991

UDC 615.462:616.314-089.28:620.1

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)

This European Standard was approved by CEN on 1991-11-04 and is identical to the ISO standard as referred to.
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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

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

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

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to this European Standard shall be published at the latest by 92-05-06 and conflicting national standards shall be withdrawn at the latest 92-05-06.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

ENDORSEMENT NOTICE

The content of this European Standard is identical with the International Standard ISO 1563 "Alginate dental impression material" published in 1990.

INTERNATIONAL STANDARD

ISO 1563

Second edition
1990-09-01

Dental alginate impression material

Produits pour empreintes dentaires à base d'alginate

Reference number
ISO 1563:1990(E)

Contents

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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.

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.

International Standard ISO 1563 was prepared by Technical Committee ISO/TC 106, *Dentistry*.

This second edition cancels and replaces the first edition (ISO 1563:1978), of which it constitutes a technical revision.

This revision of ISO 1563 differs from the first 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 °C ± 1 °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.

Introduction

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.

This page intentionally left blank

Dental alginate impression material

1 Scope

This International Standard applies to dental alginate impression materials used in dentistry to take impressions of teeth and tissues of the oral cavity. It specifies requirements for dental materials containing an alginate as essential gel-forming ingredient, which, after mixing with water in accordance with the manufacturer's instructions, is capable of reacting to form a material suitable for taking impressions.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6873:1983, *Dental gypsum products*.

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 mixing time: That part of the total working time specified or required in order to obtain a satisfactory mix.

3.2 total working time: That period of time between the start of mixing and the commencement of setting.

3.3 setting time: That period of time between the start of mixing and the achievement of the necessary elasticity to remove the impression.

4 Requirements

4.1 Powder

The powder shall be uniform and free from foreign materials (matter).

Compliance with this requirement shall be determined in accordance with 6.2.

4.2 Biocompatibility

See the introduction (p. v) for guidance on biocompatibility.

4.3 Mixed material

The material, mixed in accordance with the manufacturer's instructions, shall be homogeneous and free from lumps and granules and shall have a smooth surface; it shall form a smooth plastic mass.

Compliance with this requirement shall be determined in accordance with 6.2.

4.4 Mixing time

The mixing time, stated by the manufacturer, shall not be more than 60 s (1 min).

4.5 Total working time

When determined in accordance with 6.3, the average penetration value achieved shall not exceed 0,25 mm at the end of the total working time stated by the manufacturer.

4.6 Compatibility with gypsum and reproduction of detail

The impression material shall impart a smooth surface to, and separate cleanly from, a gypsum cast made from a recommended brand of gypsum product; this cast poured against the impression shall reproduce the 50 µm-line [see figure 3a)] without