Dental aqueous impression materials based on agar

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 1564:2001 sisaldab Euroopa standardi EN ISO 1564:1998 ingliskeelset teksti. Käesolev dokument on jõustatud 18.06.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 1564:2001 consists of the English text of the European standard EN ISO 1564:1998. This document is endorsed on 18.06.2001 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This International Standard specifies requirements for essential physical properties and other characteristics of impression matertials having reversible agar hydrocolloid as a gel-forming ingredient, along with tests specified for determining compliance with those requirements.	**Scope:** This International Standard specifies requirements for essential physical properties and other characteristics of impression matertials having reversible agar hydrocolloid as a gel-forming ingredient, along with tests specified for determining compliance with those requirements.

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Võtmesõnad:

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Descriptors: Dentistry, impression materials, agar, testing.

English version

Dental aqueous impression materials based on agar

(ISO 1564 : 1995)

Produits dentaires hydrauliques pour empreintes à base d'agar-agar (ISO 1564 : 1995)

Dentale Abformmassen auf Agarbasis (ISO 1564 : 1995)

This European Standard was approved by CEN on 1998-11-20.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the 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

International Standard

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

which was prepared by ISO/TC 106 'Dentistry' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 55 'Dentistry', the Secretariat of which is held by DIN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by May 1999 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 1564 : 1995 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative).

Contents

1 Scope

This International Standard specifies requirements for essential physical properties and other characteristics of impression materials having reversible agar hydrocolloid as a gel-forming ingredient, along with tests specified for determining compliance with those requirements. It also specifies requirements with respect to the manufacturer's instructions, and the essentials for packaging, labelling and marking.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were 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 editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6873:1983, *Dental gypsum products*.

ISO/TR 7405:1984, *Biological evaluation of dental materials*.

3 Definitions

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

3.1 gelation temperature: Temperature at which the agar impression material develops the elastic properties which will permit removal of an impression from undercuts in the mouth with only minimal distortion.

3.2 immediate container: Container which is in direct contact with the impression material.

3.3 storing: Conditioning of the material, immediately after liquefication, needed to reduce the temperature as required prior to its use in syringing, or prior to tempering.

3.4 tempering: Conditioning of the material, after the storing treatment, needed to reduce the temperature of the material as required prior to its insertion into the mouth.

4 Classification by type

Type 1 — High consistency: For making impressions of complete or partial dental arches, with or without the use of syringe-extruded increments of type 2 or type 3 materials.

Type 2 — Medium consistency: For making impressions of complete and partial dental arches, with or without the use of syringe-extruded increments, and also for use as a syringe-extruded material.

Type 3 — Low consistency: For syringe use only.

5 Requirements for characteristics and physical properties

The requirements are given in table 1.

5.1 Biocompatibility

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard, but it is recommended that reference be made to ISO/TR 7405 when assessing possible biological or toxicological hazards associated with infection or irritation of normal oral mucosa, or with the concentration of potentially toxic elements or components.