Dentistry - Hydrocolloid impression materials (ISO 21563:2013)

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 21563:2013 sisaldab Euroopa standardi EN ISO 21563:2013 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 21563:2013 consists of the English text of the European standard EN ISO 21563:2013.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 21.08.2013.	Date of Availability of the European standard is 21.08.2013.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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English Version

Dentistry - Hydrocolloid impression materials (ISO 21563:2013)

Médecine bucco-dentaire - Produits pour empreintes à base d'hydrocolloïdes (ISO 21563:2013)

Zahnheilkunde - Hydrokolloidabformmassen (ISO 21563:2013)

This European Standard was approved by CEN on 22 June 2013.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 21563:2013) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2014, and conflicting national standards shall be withdrawn at the latest by February 2014.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 21563:1991, EN ISO 13716:2000, EN ISO 1564:1998.

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Endorsement notice

The text of ISO 21563:2013 has been approved by CEN as EN ISO 21563:2013 without any modification.

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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]