SLOVENSKI STANDARD
SIST EN ISO 21563:2021

01-december-2021

Nadomešča:
SIST EN ISO 21563:2013

Zobozdravstvo - Hidrokoloidni materiali za oblikovanje (odtise) (ISO 21563:2021)

Dentistry - Hydrocolloid impression materials (ISO 21563:2021)

Zahnheilkunde - Hydrokolloidabformmaterialien (ISO 21563:2021)

Médecine bucco-dentaire - Produits pour empreintes à base d'hydrocolloïdes (ISO 21563:2021)

Ta slovenski standard je istoveten z: **EN ISO 21563:2021**

ICS:

11.060.10	Zobotehnični materiali	Dental materials

SIST EN ISO 21563:2021 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21563

September 2021

ICS 11.060.10

Supersedes EN ISO 21563:2013

English Version

Dentistry - Hydrocolloid impression materials (ISO 21563:2021)

Médecine bucco-dentaire - Produits pour empreintes à base d'hydrocolloïdes (ISO 21563:2021)

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

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Ref. No. EN ISO 21563:2021 E

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European foreword

This document (EN ISO 21563:2021) 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of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by March 2022.

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

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The text of ISO 21563:2021 has been approved by CEN as EN ISO 21563:2021 without any modification.

INTERNATIONAL STANDARD

ISO 21563

Second edition
2021-08

Dentistry — Hydrocolloid impression materials

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

Reference number
ISO 21563:2021(E)

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Published in Switzerland

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 21563:2013), which has been technically revised.

The main changes compared to the previous edition are as follows:

— The detail reproduction before and after disinfection for alginate powder and paste/paste materials has been corrected to be 50 microns.

— The elastic recovery test has been modified to allow for the use of poly(methyl methacrylate) plates as an alternative to glass or metal.

— Figures A.2, A.3, A.4, and A.6 have been corrected.

— Multiple editorial changes have been made throughout the document.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Dentistry — Hydrocolloid impression materials

1 Scope

This document specifies the requirements and test methods for hydrocolloid impression materials. This document helps to determine whether 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. This document does not address possible biological hazards associated with the materials. Assessment of these hazards is addressed in ISO 7405 and the ISO 10993 series.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
bonding
adherence of the *impression* (3.6) material components in a single impression after each of the interfacing materials has reached the level of effective setting required for successful removal from the mouth

3.2
bulk container
labelled packaging 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
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 21067-1:2016, 2.2.7, modified — "retail packaging" and "sales packaging" have been changed from preferred terms to admitted terms.]

3.4
elastic recovery
elastic properties required to recover adequately from deformation

3.5
extrusion
process of obtaining a liquefied Type 3 or Type 3A agar *impression* (3.6) material from the containing cartridge or syringe

3.6
impression
negative copy of oral or craniofacial tissue surfaces obtained by placing a mouldable impression material into contact with the tissue surfaces, and allowing it to harden, or to become elastic, such that the entire impression material/tray assembly can be removed from the contact without significant harm to the tissues or to the assembly

Note 1 to entry: A properly formed impression is capable of having a relatively fluid model (cast) forming material poured against the intaglio surface so that, when the modelling material sets, a positive copy of the impressed surfaces is formed.

3.7
initial setting time
time, measured from commencement of mixing components of a material, or otherwise activating the chemistry involved, and ending at a time when results of a prescribed test show that the activated material has begun to set at a rate indicating that the effective setting time will be reached at some predictable time thereafter

Note 1 to entry: Initial setting times stated in the manufacturer's instructions are useful to test operators, users and standards developers because they can be helpful:

— in determining whether quality of a product has deteriorated before or after opening of the packaging; for example, if the initial setting time found by the test operator or user corresponds closely to that stated in the manufacturer's instructions, it can be assumed that the product is of a quality suitable for testing or use;

— in the development of standards for certain materials when there is a need for a standard to identify a reference point in time that can be used as a basis for specifying a later point in time at which a subsequently specified procedure can safely begin.

3.8
liquefaction
process of heating an agar *impression* (3.6) or duplicating material to change it from the elastic gel state to the mouldable or pourable sol state

3.9
non-reversible impression material
impression (3.6) material which, having been brought to the effective setting stage as required for removal from the mouth, cannot be returned to the mouldable state required for forming impressions

3.10
primary packaging
primary container
DEPRECATED: immediate container
packaging designed to come into direct contact with the product

[SOURCE: ISO 21067-1:2016, 2.2.3, modified — The admitted term "primary container" and the deprecated term "immediate container" have been added.]

3.11
reversible impression material
impression (3.6) material such as an agar hydrocolloid which, after having been brought to the gel state for marketing purposes, can be heated so as to bring it to the relatively fluid colloid or paste-like state required for making an impression

Note 1 to entry: Whereas in past years the “gel to sol” and “sol to gel” reversibility capacities of such impression materials have allowed them to be recycled for repeated uses, modern infection control practices now discourage user recycling of the reversible impression materials for repeated uses in the mouth.

3.12
secondary packaging
DEPRECATED: over packaging
packaging designed to contain one or more *primary packagings* (3.10) together with any protective materials and accessory devices that may have to be provided for use with the product

[SOURCE: ISO 21067-1:2016, 2.2.4, modified — The deprecated term "over packaging" has been added; "where required" has been replaced by "and accessory devices that may have to be provided for use with the product".]

3.13
storing
process of holding increments of liquefied reversible agar hydrocolloid *impression* (3.6) material at a reduced temperature pending time they will be injected or tempered for impression making purposes

3.14
strain-in-compression
flexibility/stiffness property ranges of materials so as to determine whether the set materials, when formed as *impressions* (3.6), can be removed from the mouth without injury to impressed oral tissues and will have adequate stiffness in the more flexible portions of impressions to resist deformation when model-forming products are poured against them

3.15
tempering
process of holding a heavy or medium bodied agar *impression* (3.6) material in a slightly higher than mouth temperature water bath, after the material has been placed into an impression tray, so as to further reduce the sol state temperature as necessary for safe and effective seating in the mouth

3.16
unit packet
packaging containing only the amount of product usually needed for a single dental clinical or laboratory application

4 Classification of agar hydrocolloid impression materials

The agar impression materials are classified according to the consistencies they exhibit while they are ready for impressing against the oral or craniofacial tissue surfaces, and when tested according to 5.2.

— Type 1 heavy bodied, for making impressions of complete or partial dental arches, with or without the use of companion increments of lighter bodied Type 2 or Type 3 agar impression materials.

— Type 2 medium bodied, for making impressions of complete and partial dental arches, with or without the use of companion syringe-extruded increments of Type 3 agar materials.

— Type 3 light bodied, for syringe use with either the Type 1 or Type 2 agar materials.

— Type 3A light bodied, material formulated for syringe use in a reversible/non-reversible impression material system, and that has been claimed to be capable of bonding to a companion alginate impression material that will make up the greater part of an agar/alginate impression material system.