BS EN ISO 21563:2021

BSI Standards Publication

Dentistry — Hydrocolloid impression materials

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 21563:2021. It is identical to ISO 21563:2021. It supersedes BS EN ISO 21563:2013, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106/2, Prosthodontic materials.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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English Version

Dentistry - Hydrocolloid impression materials (ISO 21563:2021)

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

Zahnheilkunde - Hydrokolloidabformmaterialien (ISO 21563:2021)

This European Standard was approved by CEN on 3 August 2021.

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

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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of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by March 2022.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.

This document supersedes EN ISO 21563:2013.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

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Endorsement notice

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

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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

INTERNATIONAL STANDARD **ISO 21563:2021**

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