Irish Standard
I.S. EN ISO 21563:2013

Dentistry - Hydrocolloid impression materials (ISO 21563:2013)

I.S. EN ISO 21563:2013

Incorporating amendments/corrigenda/National Annexes issued since publication:

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NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie

W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

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EUROPEAN STANDARD

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EN ISO 21563

August 2013

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Supersedes EN 21563:1991, EN ISO 13716:2000, EN ISO 1564:1998

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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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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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of an identical text or by endorsement, at the latest by February 2014, and conflicting national standards shall be withdrawn at the latest by February 2014.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.

I.S. EN ISO 21563:2013

INTERNATIONAL STANDARD

ISO 21563

First edition
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Dentistry — Hydrocolloid impression materials

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

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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

ISO 21563 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This first edition of ISO 21563 constitutes a consolidation of the three standards listed below and, as such, cancels and replaces, in whole, all three of the standards listed.

— ISO 1563:1990, *Dentistry — Alginate impression materials*

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

— ISO 13716:1999, *Dentistry — Reversible/irreversible hydrocolloid impression materials systems*

Re-evaluations of all the provisions stated in the three ISO standards to be included in the consolidation led to the significant technical changes listed as follows.

— The alginate hydrocolloid impression materials (ISO 1563) are now required to be subject to the same tear strength test that has been in effect for the agar hydrocolloid impression materials (ISO 1564 and ISO 13716) instead of being subject to a compressive strength test.

— The requirement for the alginate impression material powder materials to be “free from foreign materials”, as stated in ISO 1563, has not been carried forward into the consolidation because no objective test has been specified for determining compliance with the requirement.

— The “gelation temperature” requirements in ISO 1564 and ISO 13716 have not been carried forward for the agar impression materials because results of the elastic recovery test (7.5), if conducted following the required manufacturer’s instructions for use (8.2.1 and/or 8.2.2), will indicate whether adequate gelation will take place during clinical use of the materials.

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.