

INTERNATIONAL STANDARD

ISO
3336

Second edition
1993-08-15

Dentistry — Synthetic polymer teeth

Produits et matériel pour l'art dentaire — Dents en polymères synthétiques



Reference number
ISO 3336:1993(E)
AVA Documents
Document Sharing Hub

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.

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.

International Standard ISO 3336 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Sub-Committee SC 2, *Prosthetic materials*.

This second edition cancels and replaces the first edition (ISO 3336:1977).

The main changes are as follows:

- a) revision, in accordance with ISO 7491:1985, of the procedure for the determination of colour stability;
- b) inclusion of a requirement for manufacturers to provide guidance when special treatment is required in order to achieve adequate bonding of the teeth to denture-base polymers;
- c) inclusion of a requirement for manufacturers to provide details of the dimensions of the teeth, especially the width, in order to facilitate the selection of teeth by clinicians;
- d) the hardness test for teeth has been omitted, as the crazing test (6.8) serves to identify inadequate crosslinking of the polymer.

It is proposed that at the next revision changes in the procedure in 6.6 for the determination of the quality of bonding will be considered.

© ISO 1993

All rights reserved. No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Introduction

Specific qualitative and quantitative requirements of freedom from biological hazard are not included in this International Standard, but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to ISO 10993-1:1992, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests* and ISO/TR 7405:1984, *Biological evaluation of dental materials*, or any more recent editions.

Dentistry — Synthetic polymer teeth

1 Scope

This International Standard specifies a classification, requirements and test methods for teeth which are composed of synthetic polymers such as poly(methyl methacrylate) and its copolymers, and which are manufactured for use in prostheses used in dentistry.

Terms used are in accordance with the definitions in ISO 1942-1 and ISO 1942-2.

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 483:1988, *Plastics — Small enclosures for conditioning and testing using aqueous solutions to maintain relative humidity at constant value*.

ISO 1567:1988, *Dentistry — Denture base polymers*.

ISO 1942-1:1989, *Dental vocabulary — Part 1: General and clinical terms*.

ISO 1942-2:1989, *Dental vocabulary — Part 2: Dental materials*.

ISO 3950:1984, *Dentistry — Designation system for teeth and areas of the oral cavity*.

ISO 6873:1983, *Dental gypsum products*.

ISO 7491:1985, *Dental materials — Determination of colour stability of dental polymeric materials*.

3 Classification

Synthetic polymer teeth are grouped in accordance with the following classification.

- Type 1: anterior teeth
- Type 2: posterior teeth

4 Requirements

4.1 Dimensions of teeth

When measured in accordance with 6.2, the dimensions shall be within 5 % of those stated by the manufacturer (see 7.3).

4.2 Colour and blend

Sets of anterior and posterior teeth, representing each shade from the same manufacturer, shall exhibit no perceptible colour difference between each other and the manufacturer's shade guide (7.2.1), when tested in accordance with 6.3.

4.3 Freedom from biological hazard

See the Introduction for guidance on biological hazard.

4.4 Freedom from porosity and other defects

When examined in accordance with 6.4 (but see 7.2.3), the teeth shall exhibit no porosity or defect, such as rough trimming and rough finish, on the coronal surfaces.