



**SLOVENSKI STANDARD
SIST EN ISO 10139-2:2002**

01-maj-2002

Dentistry - Soft lining materials for removable dentures - Part 2: Materials for long-term use (ISO 10139-2:1999)

Dentistry - Soft lining materials for removable dentures - Part 2: Materials for long-term use (ISO 10139-2:1999)

Zahnheilkunde - Weichbleibende Unterfütterungswerkstoffe für Prothesen - Teil 2: Werkstoffe für langzeitige Anwendung (ISO 10139-2:1999)

Art dentaire - Produits souples pour intrados de prothèses dentaires amovibles - Partie 2: Produits pour utilisation de longue durée (ISO 10139-2:1999)

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Ta slovenski standard je istoveten z: EN ISO 10139-2:2001

ICS:

11.060.10 Z[à[c @ ã } ã[æ ^ ï ã Dental materials

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10139-2

July 2001

ICS 11.060.10

English version

**Dentistry - Soft lining materials for removable dentures - Part 2:
Materials for long-term use (ISO 10139-2:1999)**

Art dentaire - Produits souples pour intrados de prothèses
dentaires amovibles - Partie 2: Produits pour utilisation de
longue durée (ISO 10139-2:1999)

Zahnheilkunde - Weichbleibende Unterfütterungswerkstoffe
für Prothesen - Teil 2: Werkstoffe für langzeitige
Anwendung (ISO 10139-2:1999)

This European Standard was approved by CEN on 4 June 2001.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 10139-2:2001 (E)**Foreword**

The text of the International Standard from Technical Committee ISO/TC 106 "Dentistry" of the International Organization for Standardization (ISO) has been taken over as an European Standard by 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 January 2002, and conflicting national standards shall be withdrawn at the latest by January 2002.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 10139-2:1999 has been approved by CEN as a European Standard without any modification.

NOTE Normative references to International Standards are listed in annex ZA (normative).

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Annex ZA
(normative)

Normative references to International Publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO 3696	1987	Water for analytical laboratory use - Specification and test methods	EN ISO 3696	1995

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INTERNATIONAL
STANDARD

ISO
10139-2

First edition
1999-10-15

**Dentistry — Soft lining materials for
removable dentures —**

**Part 2:
Materials for long-term use**

*Art dentaire — Produits souples pour intrados de prothèses dentaires
amovibles —*
Partie 2: Produits pour utilisation de longue durée

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Reference number
ISO 10139-2:1999(E)

ISO 10139-2:1999(E)**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 3.

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 10139-2 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

ISO 10139 consists of the following parts, under the general title, *Dentistry — Soft lining materials for removable dentures*:

— *Part 1: Short-term materials*

— *Part 2: Materials for long-term use*

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Introduction

Denture lining materials for long-term use are classified in this International Standard according to their softness and elasticity. Although it is not claimed that any particular level of softness or elasticity is superior to another, this classification is intended to assist clinicians because clinicians will now have more information than hitherto with which to make an informed choice.

Although water sorption and solubility are also important properties of these materials, the fact that equilibrium within the material is not achieved for months or even years discounts the usefulness of any tests for specification purposes, and requirements for these properties have therefore not been included.

It was recognized that reasons for clinical failure of this group of materials included breakdown of the bond of the soft material to the denture base and tearing of the material. Although tests for bond strength have been reported in scientific literature, it has not been possible, at the present time, to select one which ensures acceptable reproducibility when used by different test centres. It is hoped that a future revision of this part of ISO 10139 will benefit from work on this problem.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard. Information relevant to assessing possible biological or toxicological hazards is given in ISO 7405.

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