



SLOVENSKI STANDARD
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Dentistry - Soft lining materials for removable dentures - Part 2: Materials for long-term use (ISO 10139-2:2009)

Zahnheilkunde - Weiche Unterfütterungswerkstoffe für Prothesen - Teil 2: Werkstoffe für Langzeitanwendungen (ISO 10139-2:2009)

Art dentaire - Produits souples pour intrados de prothèses dentaires amovibles - Partie 2: Produits pour utilisation de longue durée (ISO 10139-2:2009)

Ta slovenski standard je istoveten z: EN ISO 10139-2:2009

ICS:

11.060.10 Z[à[c @ ã } ã æ ' ã ã Dental materials

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 10139-2

August 2009

ICS 11.060.10

Supersedes EN ISO 10139-2:2001

English Version

Dentistry - Soft lining materials for removable dentures - Part 2: Materials for long-term use (ISO 10139-2:2009)

Art dentaire - Produits souples pour intrados de prothèses
dentaires amovibles - Partie 2: Produits pour usage à long
terme (ISO 10139-2:2009)

Zahnheilkunde - Weichbleibende Unterfütterungswerkstoffe
für Prothesen - Teil 2: Werkstoffe für die
Langzeitanwendung (ISO 10139-2:2009)

This European Standard was approved by CEN on 31 July 2009.

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 CEN 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

This document (EN ISO 10139-2:2009) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with 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 February 2010, and conflicting national standards shall be withdrawn at the latest by February 2010.

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 ISO 10139-2:2001.

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

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The text of ISO 10139-2:2009 has been approved by CEN as a EN ISO 10139-2:2009 without any modification.

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INTERNATIONAL
STANDARD

ISO
10139-2

Second edition
2009-08-01

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

Part 2:
Materials for long-term use

*Art dentaire — Produits souples pour intrados de prothèses dentaires
amovibles —*

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Partie 2: Produits pour usage à long terme
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Reference number
ISO 10139-2:2009(E)

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Published in Switzerland

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ISO 10139-2:2009(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 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 10139-2 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

This second edition cancels and replaces the first edition (ISO 10139-2:1999) which has been technically revised.

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

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- SIST EN ISO 10139-2:2009
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- *Part 1: Materials for short-term use*
 - *Part 2: Materials for long-term use*

Introduction

Denture lining materials for long-term use are classified in this part of ISO 10139 according to their softness. Although it is not claimed that any particular level of softness is superior to another, this classification is intended to assist clinicians because clinicians will have more information with which to make an informed choice.

In this second edition of this part of ISO 10139, additional requirements for bond strength to denture base are added, as well as requirements for water sorption and solubility. A new test for the determination of the softness of the lining materials, the Shore A hardness test, has been introduced. This test cancels and replaces the penetration test of the first edition of this part of ISO 10139.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this part of ISO 10139. Information relevant to assessing possible biological or toxicological hazards is given in ISO 7405 and ISO 10993-1.

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