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 —

Partie 2: Produits pour usage à long terme



Reference number ISO 10139-2:2009(E)

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Cont	rents Pag	е
Forewo	ordi	v
Introdu	uction	٧
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Classification	2
5 5.1 5.2 5.3 5.4	Requirements	2 2 2
5.5 6	Solubility Sampling	
7 7.1 7.2 7.3 7.4	Test methods Test conditions Shore A hardness Bond strength Water sorption and solubility	3 3 4
8 8.1 8.2 8.3	Requirements for packaging, marking and instructions supplied by manufacturer  Packaging	9 0
Bibliog	graphy1	2

#### **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, *Prosthodontic 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*:

- 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.