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Dentistry — Soft lining materials for removable dentures —

Part 2: Materials for long-term use

Médecine bucco-dentaire — Produits souples pour intrados de prothèses dentaires amovibles —

Partie 2: Produits pour usage à long terme

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

This third edition cancels and replaces the second edition (ISO 10139-2:2009), of which it constitutes a minor revision to harmonize the definition of long-term use with other international definitions (30 days).

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*

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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.

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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Dentistry — Soft lining materials for removable dentures —

Part 2: Materials for long-term use

1 Scope

This part of ISO 10139 specifies requirements for softness, adhesion, water sorption and water solubility, as well as for packaging, marking and manufacturer's instructions for soft denture lining materials suitable for long-term use. These materials may also be used for maxillofacial prostheses.

2 Normative references

The following referenced documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 7619-1, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: Durometer method (Shore hardness)*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 20795-1, *Dentistry — Base polymers — Part 1: Denture base polymers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

3.1
soft denture lining material
soft resilient material bonded to the fitting surface of a denture to reduce trauma to the supporting tissues

3.2
long-term use
use for a period of more than 30 d

3.3
immediate container
container that is in direct contact with the material

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