



BSI Standards Publication

**Dentistry — Polymer-based luting materials
containing adhesive components**

National foreword

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**Dentistry — Polymer-based
luting materials containing
adhesive components**

*Médecine bucco-dentaire — Produits de scellement à base de
polymères contenant des composants adhésifs*



Reference number
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Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Classification	2
5 Performance issues	2
5.1 Biocompatibility.....	2
5.2 Bond strength and physical and chemical performances.....	2
6 Sampling	3
7 Test methods	3
7.1 General.....	3
7.2 Test conditions.....	3
7.3 Inspection.....	3
7.4 Preparation of test specimens.....	3
7.5 Film thickness.....	4
7.5.1 Apparatus.....	4
7.5.2 Test procedure.....	4
7.6 Working time.....	5
7.6.1 Apparatus.....	5
7.6.2 Procedure.....	5
7.7 Setting time.....	6
7.7.1 Apparatus.....	6
7.7.2 Procedure.....	7
7.8 Sensitivity to ambient light.....	8
7.8.1 Apparatus.....	8
7.8.2 Procedure.....	9
7.9 Depth of cure.....	9
7.9.1 Apparatus.....	9
7.9.2 Procedure.....	9
7.10 Flexural strength.....	10
7.10.1 Apparatus.....	10
7.10.2 Preparation of test specimens.....	11
7.10.3 Procedure.....	12
7.10.4 Treatment of results.....	12
7.11 Water sorption.....	12
7.11.1 Apparatus.....	12
7.11.2 Preparation of test specimens.....	13
7.11.3 Procedure.....	14
7.12 Colour stability.....	15
7.12.1 General.....	15
7.12.2 Apparatus.....	15
7.12.3 Preparation of test specimens.....	15
7.12.4 Procedure.....	16
7.12.5 Colour comparison.....	16
7.13 Radio-opacity.....	16
7.13.1 Preparation of test specimen.....	16
7.13.2 Test procedure.....	16
8 Packaging, marking, instructions and information to be supplied	16
8.1 Packaging.....	16
8.2 Marking.....	16

8.2.1	Capsule or single-dose container	17
8.2.2	Multi-dose container	17
8.2.3	Outermost package	17
8.3	Manufacturer's instructions and information for the user	18
Annex A (informative) Test methods to determine shear bond strength to dentine		20
Annex B (informative) Compact-sized fixing jigs for self-curing procedure		33
Annex C (informative) Bond strength to dentine and physical and chemical performances		37
Bibliography		41

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

Introduction

This document provides test methods and information of performances for polymer-based restorative materials for luting which contain adhesive components. Test methods specified in this document used for a group of materials with varying compositions has proved difficult to set performance limits. Evidence is needed from using this document to develop it into an International Standard.

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological risks are not included in this document but it is recommended that, for assessment of such biological risks, reference should be made to ISO 10993-1 and ISO 7405 .

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Dentistry — Polymer-based luting materials containing adhesive components

1 Scope

This document specifies test methods and information of bond strength to dentine and physical and chemical performances of dental polymer-based luting materials containing adhesive components. The materials are supplied in a form suitable for mechanical mixing or hand-mixing, including using auto-mixing tips, for self-curing and/or external energy activation, or non-mixing for external energy activation.

The polymer-based luting materials covered by this document are intended to be used for the cementation or fixation of restorations and appliances such as inlays, onlays, veneers, posts, crowns and bridges.

This document does not cover the following polymer-based luting materials:

- a) those which do not have an adhesive component within the structure of the material (see ISO 4049);
- b) those intended for veneering sub-frames (see ISO 10477).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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 7491, *Dental materials — Determination of colour stability*

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

ISO 13116, *Dentistry — Test method for determining radio-opacity of materials*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

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[SOURCE: ISO/TS 11405:2015, 3.1]