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**BS EN ISO 13116:2014**



**BSI Standards Publication**

# **Dentistry — Test Method for Determining Radio-Opacity of Materials**

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This British Standard is the UK implementation of EN ISO 13116:2014.

The UK participation in its preparation was entrusted to Technical Committee CH/106/1, Dental restorative and orthodontic materials.

A list of organizations represented on this committee can be obtained on request to its secretary.

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## Dentistry - Test Method for Determining Radio-Opacity of Materials (ISO 13116:2014)

Médecine bucco-dentaire - Méthodes de détermination de la radio opacité des matériaux (ISO 13116:2014)

Zahnheilkunde - Prüfverfahren zur Bestimmung der Röntgensichtbarkeit von Materialien (ISO 13116:2014)

This European Standard was approved by CEN on 6 September 2014.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
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**CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels**

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## Foreword

This document (EN ISO 13116:2014) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with 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of an identical text or by endorsement, at the latest by May 2015, and conflicting national standards shall be withdrawn at the latest by May 2015.

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.

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

### Endorsement notice

The text of ISO 13116:2014 has been approved by CEN as EN ISO 13116:2014 without any modification.

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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](http://www.iso.org/directives)).

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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 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 1, *Filling and restorative materials*.

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# Dentistry — Test Method for Determining Radio-Opacity of Materials

## 1 Scope

This International Standard specifies test methods for determination of radio-opacity of a test material by reference to a specimen of an aluminium standard. The method is designed to discriminate radio-opacity at a clinically meaningful level and is not designed to take account of factors which may affect precise, inherent values of radio-opacity such as background noise, X-ray beam power, grey scale correction and image enhancement. It is recognized that such factors can change the value of radio-opacity but not the relative ranking compared to standard thicknesses of an internal standard such as aluminium. This test may be performed with conventional or digital sensing techniques of dental X-ray apparatus.

## 2 Normative references

The following 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 3665, *Photography — Intra-oral dental radiographic film and film packets — Manufacturer specifications*

ISO 1942, *Dentistry — Vocabulary*

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

## 3 Terms and definitions

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

## 4 Requirements

This International Standard does not set pass/fail limits for radio-opacity. If a manufacturer claims that a material is radio-opaque, the radio-opacity, determined in accordance with [Clause 7](#), shall have a value at least equivalent to the minimum level specified in the appropriate product standard requirements.

NOTE Aluminium has a radio-opacity equivalent to that of dentine. Thus 1 mm of material having a radio-opacity equivalent to 1 mm of aluminium has a radio-opacity equivalent to that of dentine.

## 5 Sampling

The relevant product standard defines the details of the sampling procedure.

NOTE Normal procedures are for a sample to be drawn from one batch to provide sufficient material to complete the prescribed test. The test sample normally consists of packages prepared for retail sale.