

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 13116:2014 sisaldab Euroopa standardi EN ISO 13116:2014 inglisekeelset teksti.	This Estonian standard EVS-EN ISO 13116:2014 consists of the English text of the European standard EN ISO 13116:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
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English Version

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)

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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of an identical text or by endorsement, at the latest by May 2015, and conflicting national standards shall be withdrawn at the latest by May 2015.

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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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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 — Manufacturers 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.