



SLOVENSKI STANDARD SIST EN ISO 12836:2012

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Zobozdravstvo - Digitalne naprave za uporabo sistemov CAD/CAM za posredne zobne restavracije/obnovo - Preskusne metode za ugotavljanje točnosti (ISO 12836:2012)

Dentistry - Digitizing devices for CAD/CAM systems for indirect dental restorations - Test methods for assessing accuracy (ISO 12836:2012)

Zahnheilkunde - Digitalisierungsgeräte für CAD/CAM-Systeme für indirekte dentale Restaurationen - Prüfverfahren zur Beurteilung der Genauigkeit (ISO 12836:2012)

Médecine bucco-dentaire - Dispositifs de numérisation des systèmes CAD/CAM pour restaurations dentaires indirectes - Méthodes d'essai pour l'exactitude d'évaluation (ISO 12836:2012)

Ta slovenski standard je istoveten z: EN ISO 12836:2012

ICS:

11.060.01	Zobozdravstvo na splošno	Dentistry in general
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

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EUROPEAN STANDARD
 NORME EUROPÉENNE
 EUROPÄISCHE NORM

EN ISO 12836

September 2012

ICS 11.060.01

English Version

Dentistry - Digitizing devices for CAD/CAM systems for indirect dental restorations - Test methods for assessing accuracy (ISO 12836:2012)

Médecine bucco-dentaire - Dispositifs de numérisation des systèmes de CFAO pour restaurations dentaires - Méthodes d'essai pour l'évaluation de l'exactitude (ISO 12836:2012)

Zahnheilkunde - Digitalisierungsgeräte für CAD/CAM-Systeme für indirekte dentale Restaurationen - Prüfverfahren zur Beurteilung der Genauigkeit (ISO 12836:2012)

This European Standard was approved by CEN on 14 September 2012.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Contents

Page

Foreword.....3

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[SIST EN ISO 12836:2012](https://standards.iteh.ai/catalog/standards/sist/72489d05-8846-44af-8251-756dfdf91d59/sist-en-iso-12836-2012)

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Foreword

This document (EN ISO 12836:2012) has been prepared by Technical Committee ISO/TC 106 "Dentistry" in collaboration with Technical Committee 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 March 2013, and conflicting national standards shall be withdrawn at the latest by March 2013.

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 organisations 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.

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The text of ISO 12836:2012 has been approved by CEN as a EN ISO 12836:2012 without any modification.

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INTERNATIONAL STANDARD

ISO
12836

First edition
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Dentistry — Digitizing devices for CAD/CAM systems for indirect dental restorations — Test methods for assessing accuracy

*Médecine bucco-dentaire — Dispositifs de numérisation des systèmes
de CFAO pour restaurations dentaires — Méthodes d'essai pour
l'évaluation de l'exactitude*

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Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	4
4.1 General	4
4.2 Accuracy	4
5 Test methods	4
5.1 General	4
5.2 Test conditions	4
5.3 Accuracy	5
6 Test report	5
Annex A (normative) Inlay-shaped specimen	6
Annex B (normative) Crown- and bridge-shaped specimens	10
Annex C (normative) Sphere	14
Bibliography	17

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 12836:2012](https://standards.iteh.ai/catalog/standards/sist/72489d05-8846-44af-8251-756dfd91d59/sist-en-iso-12836-2012)

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ISO 12836:2012(E)**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 12836 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 9, *Dental CAD/CAM systems*.

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Introduction

The application of dental CAD/CAM systems is increasing throughout the world.

This International Standard specifies three test methods for assessing the accuracy of dental digitizing devices used for CAD/CAM systems.

This International Standard is based on the premise that only the matched point cloud and the resulting Standard Tessellation Language surface (STL surface) thereof be regarded as the product of scanning the physical object.

This International Standard includes the measurement of the image that is digitized from dental scanners (intra-oral scanners, lab-based optical scanners and lab-based mechanical contact scanners). Digitized images are not only used for the fabrication of restorative products but also applied to teaching and research in dentistry, in such areas as occlusion, tooth and gingival contour change measurements, and so forth.

It was felt that, besides the sphere, more physical objects are required, for example a surface with an inlay-shaped cavity with a sharp edge to simulate the edge of an inlay preparation. When no means (for example software algorithm) are available to calculate a standard deviation of discrepancies between the points of the point cloud or STL surface and the physical object's surface as a measure for accuracy, some software is required to match the CAD STL formatfile of the physical object with the point cloud or STL surface and visualize discrepancies, resulting in a qualitative assessment.

The following three specimens (two dental and one technical), which are specified in Annexes A, B and C, can be used for assessing digitizing devices:

- a) inlay-shaped specimen in order to simulate inlay-shaped cavities;
- b) multi-unit specimen, consisting of two full coverage dies with a centre-to-centre distance of 30 mm, being designed to simulate digitizing a 4-unit-bridge;
- c) a sphere, the measurement of which is limited to the hemisphere lying above the horizontal plane.

ISO 5725-1 uses two terms, "trueness" and "precision", to describe the accuracy of a measurement method. "Trueness" refers to the closeness of agreement between the arithmetic mean of a large number of test results and the true or accepted value. "Precision" refers to the closeness of agreement between test results. The general term "accuracy" is used to refer to both trueness and precision.