

**Dentistry - Minimal dental implant data set for clinical use (ISO 16498:2013)**

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Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 24.07.2013.	Date of Availability of the European standard is 24.07.2013.
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English Version

Dentistry - Minimal dental implant data set for clinical use (ISO  
16498:2013)

Médecine bucco-dentaire - Informations cliniques  
minimales requises pour les porteurs d'implants dentaires  
(ISO 16498:2013)

Zahnheilkunde - Mindestdatensatz für Dentalimplantate für  
die klinische Anwendung (ISO 16498:2013)

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## Foreword

This document (EN ISO 16498:2013) 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of an identical text or by endorsement, at the latest by January 2014, and conflicting national standards shall be withdrawn at the latest by January 2014.

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### Endorsement notice

The text of ISO 16498:2013 has been approved by CEN as EN ISO 16498:2013 without any modification.

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## Introduction

Dental implant treatment is a widely employed therapeutic procedure using endosseous devices which have a service life of many decades, although the restorations that they stabilize not infrequently require maintenance during this period. Uniquely, for such an extensively utilized technique, procedures are largely dependent upon the availability of pre-manufactured precision components. These are typically device-specific and frequently subject to design changes as manufacturers develop their products. Treatment of a patient who has had a dental implant body or bodies placed in their jaw(s) requires the availability of accurate information concerning the implants and any connecting components and adjunctive devices that have been utilized. This standard describes a minimum data set for meeting this requirement. The data may also have research, forensic and medico-legal benefits.

This minimal data set is intended to facilitate the care of patients who have been treated with dental implants by recording the relevant details of the inserted device(s) and any associated connecting components and adjunctive devices. It does not define the totality of the information that should be collected in connection with any such treatment, which is the responsibility of the relevant clinician(s).

# Dentistry — Minimal dental implant data set for clinical use

## 1 Scope

This International Standard specifies the minimal data set to be recorded for a patient receiving dental implant treatment. This will comprise the locations and types of dental implant bodies, connecting components and adjunctive devices, including grafting materials, placed in a patient's jaw(s).

This information will be recorded by the responsible clinician in the patient's file and should be made available to the patient by the clinician(s) who provided the care.

## 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 1942, *Dentistry — Vocabulary*

ISO 3950, *Dentistry — Designation system for teeth and areas of the oral cavity*

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 and the following apply.

### 3.1

#### **data set**

specification of linked data elements that comprise a unique relationship

### 3.2

#### **dental implant**

device especially designed to be placed surgically within, through or upon the bones of the craniofacial complex, the primary purposes of which are to support a dental prosthesis and to resist its displacement

[SOURCE: ISO 1942:2009, 2.71, modified — terminology has changed.]

### 3.3

#### **connecting components**

individual parts or components that can be joined to the implant body to provide support for the function of the implant

[SOURCE: ISO 1942:2009, 2.72, modified — term and definition have changed.]

### 3.4

#### **grafting materials**

material of allogenic, alloplastic, xenographic or autogenic origin which is implanted or transplanted to replace or repair defective or damaged human tissue

## 4 General information

### 4.1 Patient's identification