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Irish Standard
I.S. EN ISO 16498:2013

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

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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of an identical text or by endorsement, at the latest by January 2014, and conflicting national standards shall be withdrawn at the latest by January 2014.

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**Dentistry — Minimal dental implant
data set for clinical use**

*Médecine bucco-dentaire — Informations cliniques minimales
requises pour les porteurs d'implants dentaires*



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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. www.iso.org/directives

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The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

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).

I.S. EN ISO 16498:2013

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

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