



SLOVENSKI STANDARD SIST EN ISO 14727:2000

01-januar-2000

Dental implants - Prefabricated parts connecting suprastructures to dental implants - Contents of technical file (ISO 14727:1998)

Dental implants - Prefabricated parts connecting suprastructures to dental implants - Contents of technical file (ISO 14727:1998)

Dentalimplantate - Vorgefertigte Teile zur Verbindung von Suprastrukturen mit Dentalimplantaten - Inhalt der technischen Dokumentation (ISO 14727:1998)

Implants dentaires - Organes préfabriqués destinés à relier les suprastructures aux implants dentaires - Contenu du dossier technique (ISO 14727:1998)

<https://standards.iteh.ai/catalog/standards/sist/ec265b42-723e-4d22-bfbc-2f1ffd59a67/sist-en-iso-14727-2000>

Ta slovenski standard je istoveten z: EN ISO 14727:1998

ICS:

11.060.15 Zobni implantati Dental implants

SIST EN ISO 14727:2000 en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 14727

October 1998

ICS 11.060.20

Descriptors: see ISO document

English version

Dental implants - Prefabricated parts connecting suprastructures
to dental implants - Contents of technical file (ISO/FDIS
14727:1998)

Implants dentaires - Organes préfabriqués destinés à relier
les suprastructures aux implants dentaires - Contenu du
dossier technique (ISO/FDIS 14727:1998)

Dentalimplantate - Vorgefertigte Teile zur Verbindung von
Suprastrukturen mit Dentalimplantaten - Inhalt der
technischen Dokumentation (ISO/FDIS 14727:1998)

This European Standard was approved by CEN on 26 September 1998.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard ISO 14727:1998 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 April 1999, and conflicting national standards shall be withdrawn at the latest by April 1999.

Endorsement notice

The text of the International Standard ISO 14727:1998 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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Annex ZA (normative)
Normative references to international publications
with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 1942-1	1989	Dental vocabulary - Part 1: General and clinical terms	EN 21942-1	1991
ISO 8601	1988	Data elements and interchange formats - Information interchange - Representation of dates and times (including technical corrigendum 1:1991)	EN 28601	1992
ISO 10993-1	1997	Biological evaluation of medical devices - Part 1: Evaluation and testing	EN ISO 10993-1	1997

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INTERNATIONAL STANDARD

ISO
14727

First edition
1998-10-01

Dental implants — Prefabricated parts connecting suprastructures to dental implants — Contents of technical file

*Implants dentaires — Organes préfabriqués destinés à relier les
suprastructures aux implants dentaires — Contenu du dossier technique*

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Reference number
ISO 14727:1998(E)

ISO 14727:1998(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 3.

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.

International Standard ISO 14727 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

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Introduction

The functions of the masticatory system can be restored with implant-retained prostheses. Such prosthetic suprastructures are joined to the dental implants by "connecting parts" that provide an appropriate means of fixation.

Quality system requirements as laid down in ISO 9001 and ISO 13485 call for a file containing documents defining the product specifications for each type/model of medical device.

This International Standard specifies particular technical information to be contained in such a file for prefabricated parts connecting dental suprastructures to dental implants, termed a technical file for this purpose.

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