

**SLOVENSKI STANDARD  
SIST EN ISO 13504:2012****01-oktober-2012**

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**Zobozdravstvo - Splošne zahteve za instrumente in pripadajoči pribor, ki se uporablja pri nameščanju in vstavitvi dentalnih vsadkov (implantatov) (ISO 13504:2012)**

Dentistry - General requirements for instruments and related accessories used in dental implant placement and treatment (ISO 13504:2012)

Zahnheilkunde - Allgemeine Anforderungen an bei der Implantation verwendete Instrumente und Zubehör (ISO 13504:2012)

Médecine bucco-dentaire - Exigences générales pour instruments et accessoires utilisés en implantologie dentaire (ISO 13504:2012)

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**Ta slovenski standard je istoveten z: EN ISO 13504:2012**

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EUROPEAN STANDARD

EN ISO 13504

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2012

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English Version

## Dentistry - General requirements for instruments and related accessories used in dental implant placement and treatment (ISO 13504:2012)

Médecine bucco-dentaire - Exigences générales relatives aux instruments et aux accessoires connexes utilisés en implantologie dentaire (ISO 13504:2012)

Zahnheilkunde - Allgemeine Anforderungen an bei der Implantation verwendete Instrumente und Zubehör (ISO 13504:2012)

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

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CEN members are the national standards bodies of 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 United Kingdom.



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## Foreword

This document (EN ISO 13504:2012) 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of an identical text or by endorsement, at the latest by January 2013, and conflicting national standards shall be withdrawn at the latest by January 2013.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.

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The text of ISO 13504:2012 has been approved by CEN as a EN ISO 13504:2012 without any modification.

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# INTERNATIONAL STANDARD

**ISO**  
**13504**

First edition  
2012-07-15

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## Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment

*Médecine bucco-dentaire — Exigences générales relatives aux  
instruments et aux accessoires connexes utilisés en implantologie dentaire*

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**ISO 13504:2012(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 13504 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

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## Introduction

The use of dental implants is increasing throughout the world. Due to improved and new applications of dental implants, the need for better instruments and related accessories to be used in the placement of dental implants and the further manipulation of connecting parts in the craniofacial area is also growing. Dental implants need to be approved by local authorities.

However, instruments used in the placement of dental implants are different and need a different approval procedure. This International Standard is intended to harmonize the approval procedures and to reduce the costs caused by repeated approval and test procedures in different countries.

Materials present in instruments used in dental implant procedures have proven to be well tolerated. Potential adverse reactions cannot be totally ruled out but such reactions are to be mitigated.

However, long-term clinical experience of the use of the materials referred to in this International Standard has shown that an acceptable level of biological response can be expected when they are used in appropriate applications and when instruments are manufactured under appropriate design considerations and processes.

Due to different stainless steel standards, Annex B has been added. This gives cross-references to designations of stainless steels which are listed in other international, regional or national standards designation systems.

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