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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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Foreword

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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*.

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.