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**Dentistry — Materials for dental  
instruments —**

**Part 1:  
Stainless steel**

*Médecine bucco-dentaire — Matériaux pour instruments dentaires —  
Partie 1: Acier inoxydables*



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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 (see [www.iso.org/directives](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 21850 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

There is an increasing number of newly developed dental surgical techniques with an increasing number of procedures such as dental implant placements. The market for the dental instrument is also rapidly growing with demands for new and better instruments.

This document is intended to harmonize the approval procedures and to reduce the costs caused by repeated approval and test procedures in different countries with regard to the stainless steel materials used in dental instruments.



# Dentistry — Materials for dental instruments —

## Part 1: Stainless steel

### 1 Scope

This document specifies stainless steel commonly used in manufacturing dental instruments.

It is applicable to stainless steel materials used to manufacture either an entire instrument or a part of the instrument.

It is applicable to single-use and reusable dental instruments, whether it is or it is not connected to a power-driven system.

This document is not applicable to devices and instruments used long-term in the mouth of the patient (e.g. crown, bridges, implants) or to devices and instruments not made of stainless steel.

It contains a current selection of stainless steels suitable for use in the manufacture of dental instruments.

### 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. 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 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 15510, *Stainless steels — Chemical composition*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

#### 3.1

##### **dental instrument**

tool specially designed for use in dentistry

#### 3.2

##### **stainless steel**

steel whose most characterizing element is chromium of at least 10,5 % (mass fraction) Cr and maximum 1,2 % (mass fraction) C, and the primary importance of which is its resistance to corrosion