

**SLOVENSKI STANDARD**  
**oSIST prEN ISO 21850-1:2019**  
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**Zobozdravstvo - Materiali za dentalne instrumente - 1. del: Nerjavno jeklo (ISO/DIS 21850-1:2019)**

Dentistry - Materials for dental instruments - Part 1: Stainless steel (ISO/DIS 21850-1:2019)

Zahnheilkunde - Werkstoffe für Dentalinstrumente - Teil 1: Nichtrostende Stähle (ISO/DIS 21850-1:2019)

Médecine bucco-dentaire - Matériaux pour instruments dentaires - Partie 1: Partie 1: Acier inoxydables (ISO/DIS 21850-1:2019)

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# DRAFT INTERNATIONAL STANDARD

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## Dentistry — Materials for dental instruments —

### Part 1: Stainless steel

*Médecine bucco-dentaire — Matériaux pour instruments dentaires —*

*Partie 1: Acier inoxydables*

ICS: 11.060.20

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## ISO/DIS 21850-1:2019(E)

### Foreword

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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)).

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For an explanation on 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 the following URL: [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*.

## Introduction

There is increasing number of newly developed dental surgical techniques with increasing number of procedures such as dental implant placements. 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.

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# 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 single-use and reusable dental instruments, connected to a power-driven system or not.

This document is not applicable to devices and instruments used for long-time in the mouth of the patient (e.g. crown, bridges, implants).

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 7153-1, *Surgical instruments — Materials — Part 1: Metals*

ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

ISO 10474, *Steel and steel products — Inspection documents*

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

ISO 13504, *Dentistry — General requirements for instruments and related accessories used in dental implant placement and treatment*

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:

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

#### 3.1

##### **dental instrument**

tool specially designed for use in dentistry

## ISO/DIS 21850-1:2019(E)

## 3.2

**stainless steel**

steel, the main alloying element of which 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

## 3.2.1

**austenitic stainless steel**

corrosion-resistant steel, typically with composition of less than 0,2 % (mass fraction) C, at least 16% (mass fraction) Cr, typically about 18 % (mass fraction) Cr and over 8 % (mass fraction) Ni, which cannot be hardened by heat treatment

## 3.2.2

**martensitic stainless steel**

corrosion-resistant steel with low to medium carbon, with at least 0,1 % (mass fraction) C and between 12 % (mass fraction) and 19 % (mass fraction) Cr, which can be hardened by quenching and tempering

## 3.2.3

**precipitation-hardening stainless steel**

corrosion-resistant steel with a high strength resulting from the precipitation of intermetallic compounds (the formation of very fine intermetallic phases, carbides and Laves phases in the structure) by a final heat treatment at relatively low temperature

## 3.2.4

**ferritic stainless steel**

corrosion-resistant steel with low carbon, with less than 0,1 % (mass fraction) C and between 10,5 % (mass fraction) and 30 % (mass fraction) Cr, but which cannot be hardened by heat treatment, while a few special grades may contain nickel up to a maximum of 2,5 % and molybdenum to a maximum of 4,5 %

## 4 Materials

## 4.1 Material designation

The specification of the chemical composition and the material designation of the stainless steel shall be in accordance with ISO 15510, if applicable. There can be minor differences in chemical compositions stainless steel grades that are considered to equivalent to one another, where details can be found in [Annex A](#).

## 4.2 Composition of stainless steels

In [Table 1](#), [2](#), [3](#), and [4](#), composition of various stainless steels that are used for the manufacture of instruments used in dentistry are listed.

Table 1 — Austenitic stainless steels (Composition)

Number assigned in this standard	% (mass fraction), maximum values unless indicated otherwise									
	C	Si	Mn	P	S <sup>a</sup>	N	Cr	Mo	Ni	Others
A1	0,02	0,75	2,00	0,035	0,015	0,15	19,0 to 22,0	4,0 to 5,0	23,5 to 26,0	Cu: 1,00 to 2,00
A2	0,03	1,00	2,00	0,045	0,030	0,12 to 0,22	17,5 to 19,5	—	8,0 to 11,0	—
A3	0,03	1,00	2,00	0,025	0,015	0,10	17,0 to 19,0	2,5 to 3,2	13,0 to 15,0	—

<sup>a</sup> Particular ranges of sulfur mass fraction may provide improvement in certain properties. For polishability, a controlled sulfur mass fraction of 0,015 % maximum is recommended.

<sup>b</sup> Stainless steel is not listed in ISO 15510, but listed in EN 10088-1.