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Dentistry - Materials for dental instruments - Part 1: Stainless steel (ISO 21850-1:2020)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 21850-1

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ICS 11.060.20

English Version

Dentistry - Materials for dental instruments - Part 1: Stainless steel (ISO 21850-1:2020)

Médecine bucco-dentaire - Matériaux pour instruments dentaires - Partie 1: Partie 1: Acier inoxydables (ISO 21850-1:2020)

Zahnheilkunde - Werkstoffe für Dentalinstrumente - Teil 1: Nichtrostende Stähle (ISO 21850-1:2020)

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European foreword

This document (EN ISO 21850-1:2020) 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of an identical text or by endorsement, at the latest by November 2020, and conflicting national standards shall be withdrawn at the latest by November 2020.

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INTERNATIONAL STANDARD

ISO 21850-1

First edition
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Dentistry — Materials for dental instruments —

Part 1: Stainless steel

Médecine bucco-dentaire — Matériaux pour instruments dentaires —

Partie 1: Acier inoxydables

Reference number
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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).

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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.

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.

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.

INTERNATIONAL STANDARD **ISO 21850-1:2020(E)**

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*

