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Stomatológia Všeobecné požiadavky na ručné nástroje Časť 1: Bezkĺbne ručné nástroje (ISO 4865-1: 2023)

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Dentistry - General requirements of hand instruments - Part 1: Non-hinged hand instruments (ISO 4865-1:2023)

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

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Dentistry - General requirements of hand instruments - Part 1: Non-hinged hand instruments (ISO 4865-1:2023)

Médecine bucco-dentaire - Exigences générales relatives aux instruments à main - Partie 1: Instruments à main non articulés (ISO 4865-1:2023)

Zahnheilkunde - Teil 1: Allgemeine Anforderungen an gelenklose Handinstrumente (ISO 4865-1:2023)

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EN ISO 4865-1:2023 (E)

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European foreword

This document (EN ISO 4865-1:2023) 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.

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Dentistry — General requirements of hand instruments —

Part 1: **Non-hinged hand instruments**

Médecine bucco-dentaire — Exigences générales relatives aux instruments à main —

Partie 1: Instruments à main non articulés



STN EN ISO 4865-1: 2024

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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.

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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).

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ISO 4865-1:2023(E)

Introduction

Non-hinged hand instruments used in dentistry share many common characteristics including material properties and requirements for reprocessing. Despite the many common features among different categories of instruments, there is currently much variation in the published requirements and test methods. This document addresses these common characteristics and provides a normative reference to help reduce variation and to lead to a harmonization of standards for non-hinged hand instruments.

Dentistry — General requirements of hand instruments —

Part 1:

Non-hinged hand instruments

1 Scope

This document specifies requirements and test methods common to all non-hinged hand instruments used in dentistry, including materials, hardness, surface finish, resistance to reprocessing and information for marking, although some can have additional specific requirements and test methods.

This document does not specify terms and definitions or classification of specific types of hand instruments.

This document excludes powered instruments. The classification and the shape of working ends of non-hinged hand instruments are excluded from this document.

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 6507-1, Metallic materials — Vickers hardness test — Part 1: Test method

ISO 6508-1:2016, Metallic materials — Rockwell hardness test — Part 1: Test method

ISO 15223-1, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

ISO 17664-1, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

ISO 17664-2, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices

ISO 20417, Medical devices — Information to be supplied by the manufacturer

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