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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1952.1-2024

**Dentistry - Materials for dental instruments - Part 1: Stainless
steel**

牙科学 牙科器械用材料 第1部分：不锈钢
(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document is part 1 of YY/T 1952 "Materials for use in dental instruments in dentistry". YY/T 1952 has been published in the following parts.

--- Part 1: Stainless steel.

This document is modified to adopt ISO 21850-1:2020 "Dentistry - Materials for dental instruments - Part 1: Stainless steel".

The technical differences between this standard and ISO 21850-1:2020 and their reasons are as follows.

--- Replaced ISO 1942 with the normative reference GB/T 9937 to adapt to my country's technical conditions and increase operability;

--- Replaced ISO 7405 with YY/T 0268;

- Replaced ISO 10993-1 with the normative reference GB/T 16886.1 to adapt to my country's technical conditions and increase operability;
- Replaced ISO 15510 with the normative reference GB/T 20878;
- Replaced ISO 10474 with the normative reference GB/T 18253;
- Changed the biological evaluation standard in paragraph 2 of Chapter 6 from "ISO 10993-1" to "YY/T 0268 and GB/T 16886.1".

The following editorial changes were made to this document.

- Changed the word order of the scope of application;
- Deleted the notes on data sources in Tables 1 to 4;
- Changed the name of 5.2 from "Certificate of Analysis" to "Ingredient Confirmation";
- Deleted the content of Appendix A on the source of stainless steel ingredients.

Introduction

The number of newly developed dental surgical techniques continues to increase as the number of procedures such as dental implant placement increases.

Due to the demand for instruments, the dental equipment market is also growing rapidly.

YY/T 1952 "Dentistry - Materials for Dental Instruments" is intended to consist of two parts.

- Part 1: Stainless steel. The purpose is to standardize the selection of stainless steel materials for dental instruments and the requirements for preclinical evaluation.
- Part 2: Polymers. The purpose is to standardize the selection of polymer materials for dental devices and the requirements for preclinical evaluation.

Dentistry Materials for dental instruments Part 1: Stainless steel

1 Scope

This document specifies the stainless steel materials currently commonly used in the manufacture of dental devices, the requirements for material selection and preclinical evaluation of their performance.

This document applies to stainless steel materials used in the manufacture of equipment in whole or in part.

This document applies to disposable and reusable dental instruments, whether or not connected to a powered drive system.

This document does not apply to appliances and instruments that are used in the patient's mouth for a long time (such as crowns, bridges, implants) or appliances that are not made

of stainless steel.

and instruments.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to this document.

GB/T 9937 Dental Terminology (GB/T 9937-2020, ISO 1942:2009, MOD) GB/T 16886.1 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process (GB/T 16886.1-2022, ISO 10993-1:2018, IDT) GB/T 18253 Types of inspection documents for steel and steel products (GB/T 18253-2018, ISO 10474-2013, IDT) GB/T 20878 Stainless steel and heat-resistant steel grades and chemical compositions YY/T 0268 Dentistry Biological Evaluation of Oral Medical Devices Unit 1. Evaluation and Testing (YY/T 0268-2008, ISO 7405:2008, NEQ)

3 Terms and definitions

The terms and definitions defined in GB/T 9937 and the following apply to this document.

Dental Instruments dental instrument Instruments and tools specially designed for dentistry.

Stainless steel

Steel with corrosion resistance as its main characteristic and a chromium content of at least 10.5% (mass fraction) and a carbon content of no more than 1.2% (mass fraction).

3.2.1

Stainless steels, which usually contain less than 0.2% carbon (mass fraction) and at least 16% chromium (mass fraction), cannot be hardened by heat treatment.

Note: Generally, the chromium content is about 18% (mass fraction) and the nickel content is greater than 8% (mass fraction).

3.2.2

Low-medium carbon steel with a carbon content of at least 0.08% (mass fraction) and a chromium content between 11.5% (mass fraction) and 19% (mass fraction)