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

YY/T 1974-2025

Dentistry - Multifunction handpieces

牙科学 多功能喷枪

(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is modified to adopt ISO 22569:2020 "Dental Science - Multi-functional spray guns".

The technical differences between this document and ISO 22569:2020, and the reasons therefor, are as follows.

---IEC 60601-1 has been replaced with the normatively referenced GB 9706.1 to adapt to my country's technical conditions and increase operability;

---IEC 80601-2-60 has been replaced with the normatively referenced GB 9706.260 to adapt to my country's technical conditions and increase operability.

Actual nature;

- ISO 1942 has been replaced with the normatively referenced GB/T 9937 to adapt to my country's technical conditions and increase operability;
 - ISO 15223-1 has been replaced with the normatively referenced YY/T 0466.1 to adapt to my country's technical conditions and increase operability;
 - ISO 9687 has been replaced with the normatively referenced YY/T 0628 to adapt to my country's technical conditions and increase operability;
 - ISO 17664 has been replaced with the normatively referenced YY/T 0802 to adapt to my country's technical conditions and increase operability;
 - ISO 7494-1 has been replaced with the normatively referenced YY/T 1043.1 to adapt to my country's technical conditions and increase operability;
 - ISO 21530 has been replaced with the normatively referenced YY/T 1400 to adapt to my country's technical conditions and increase operability;
 - IEC 62366 has been replaced with the normatively referenced YY/T 1474 to adapt to my country's technical conditions and increase operability;
 - ISO 21531 has been replaced with the normatively referenced YY/T 1501 to adapt to my country's technical conditions and increase operability;
 - Added a statement regarding the scope of this document;
 - Added an example of a multi-functional spray gun with an angled bend [see Figure 1b];
 - Added an example of a straight multi-functional spray gun [see Figure 2b];
 - The pull-out force of the nozzle has been changed, and "This requirement applies only to dental treatment machines intended for use with those conforming to ISO 7494-1".
- The phrase "spray gun" has been changed to "This requirement applies only to spray guns intended for use with dental treatment machines" (see 5.2.2), adapting to the expected and feasible use.
- The condition of the spray gun used with the transferred dental treatment unit;
- Section 5.4 "Materials" has been deleted, and a recommended evaluation explanation has been added to the introduction to adapt to the specific domestic situation;
 - The wording of the test method for "surface" has been changed (see 5.5);
 - The air source has been changed, and "This requirement applies to spray guns intended for use with dental treatment machines conforming to ISO 7494-1" has been changed to...
- "These requirements apply to spray guns intended for use with dental treatment units" (see 5.6), to accommodate intended and transferable dental treatments.
- Information on the spray guns used with the machine;

---The wording of the experimental method for "repeated treatment" has been changed (see 5.16);

---The connection and supply have been changed to "This requirement applies to multifunctional dental treatment units intended for use with dental treatment units conforming to ISO 7494-1".

Multi-functional spray gun. A multi-functional spray gun is suitable for use without the need for any special tools, from dental treatment machines conforming to ISO 7494-1.

The instrument hose was disconnected and reconnected. This requirement is changed to "This requirement applies to multi-functional sprayers intended for use with dental treatment machines." Gun. The multi-functional spray gun should be disconnected from the instrument hose of the dental treatment machine and reconnected without using any special tools.

Connection." (See 5.20) to accommodate the intended use of spray guns with portable dental treatment units;

---The "Test Report" section from May 22nd has been removed to better suit the specific circumstances in China;

---Increased the maximum permissible error for the protractor (see 7.3.1.2), improving operability;

---The instructions for use, maintenance, and repair have been changed, replacing "a) the name and/or trademark and address of the manufacturer or distributor" with "a) the manufacturer's name and/or trademark and address".

Manufacturer's name and/or trademark and address (see Chapter 8) to suit the specific circumstances in the country;

---The phrase "Working parts or their packaging should have a production code" has been removed from "Multi-function spray gun" (see 10.2).

The following editorial changes have been made to this document.

---The introductory text regarding the URLs to the ISO and IEC terminology databases in section 3, "Terms and Definitions," has been removed;

---The footnote about NL/min in section 5.6 "Gas Source" has been deleted.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document was prepared by the National Technical Committee on Standardization of Dental Materials and Instruments, Subcommittee on Dental Equipment and Instruments

(SAC/TC99) SC1) is under the jurisdiction of the relevant authorities.

Introduction

This document does not include qualitative and quantitative requirements for potential biological hazards, but it is recommended to refer to [the relevant documentation] when assessing potential biological hazards.

GB/T 16886.1.

See Appendix A for a sample test report.

Dental Multi-functional Spray Gun

1 Scope

This document specifies the classification, requirements, sampling, testing methods, instructions for use, and technical specifications for multi-functional spray guns intended for use in patients' oral cavity.

Marking, labeling, and packaging.

This document applies to multi-functional spray guns used in patients' oral cavity.

This document does not apply to dental handpieces and motors, digital dental monitors, dental light curing machines, active scalers, sandblasting handpieces, or polishing hands.

Machine, suction cannula, and saliva suction device.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB 9706.1 Medical electrical equipment - Part 1: General requirements for basic safety and basic performance (GB 9706.1-2020) IEC 60601-1:2012, MOD) GB 9706.260 Medical electrical equipment - Part 2-60.Particular requirements for basic safety and basic performance of dental equipment (GB 9706.260-2020,IEC 80601-2-60:2012,MOD) GB/T 9937 Terminology in Dentistry (GB/T 9937-2020, ISO 1942:2009, MOD) YY/T 0466.1 Symbols for medical devices used to provide information to manufacturers - Part 1: General requirements (YY/T 0466.1-2023, ISO 15223-1:2021, MOD) YY/T 0628 Graphical Symbols for Dental Equipment (YY/T 0628-2020, ISO 9687:2015 AMD1.2018) IDT) YY/T 0802 Handling of Medical Devices - Information provided by medical device manufacturers (YY/T