

ICS 11.080
CCS C59



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 30689-2026

Replacing GB 30689-2014

**Hygienic requirements for automated washer-disinfector for
endoscope**

内镜自动清洗消毒机卫生要求

Issued on: January 28, 2026

Implemented on: February 1, 2027

**Issued by: State Administration for Market Regulation;
Standardization Administration of China**

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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 replaces GB 30689-2014 "Hygienic Requirements for Automatic Endoscope Cleaning and Disinfection Machines". Compared with GB 30689-2014, the main differences are in the structural design. Aside from integration and editorial changes, the main technical changes are as follows:

- The scope has been changed (see Chapter 1, Chapter 1 of the.2014 edition);
- Terminology and definitions have been changed (see Chapter 3, Chapter 3 of the.2014 edition);
- The section "Name and Model" has been removed (see Chapter 4 of the.2014 edition);
- Performance requirements have been changed, and general requirements have been added (see 4.1, Chapter 5 of the.2014 version);
- The requirements for leak detection, cleaning, disinfection temperature, and terminal rinsing have been changed (see 4.2, 4.3, 4.4.2, 4.5;
- 5.2 in the.2014 edition). 5.3.1, 5.3.2, 5.4);
- Control requirements have been changed (see 5.1.4,
- 6.4 in the.2014 version);
- Added requirements for record-keeping and traceability systems (see 5.4);
- Added health indicators and testing methods (see Chapter 6);

---The electrical safety requirements have been removed (see Chapter 7 of the 2014 edition);

---Added requirements for nameplates and instruction manuals (see 8.1, 8.2). 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 and is under the jurisdiction of the National Center for Disease Control and Prevention. The release history of this document and the document it replaces is as follows:

1 Scope

GB 30689-2026 is the Chinese national standard on hygienic requirements for automated washer-disinfector for endoscope, in the field of health care technology. It carries no /T suffix, which in the Chinese system means compliance is mandatory: a product or a practice within its scope has to meet it to be lawfully made, sold or carried out in China. It was issued on 28 January 2026 by the State Administration for Market Regulation; Standardization Administration of China, and takes effect on 1 February 2027.

Classification: ICS 11.080, CCS C59. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document specifies the performance requirements, control requirements, hygiene standards, transportation, storage and packaging, labeling, and nameplates for automated endoscope cleaning and disinfection machines. The instructions for use describe the testing methods for hygiene indicators. This document applies to automated cleaning and sterilization machines for flexible endoscopes.

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/T 191 Packaging and Storage Graphic Symbols

GB 5749 Standard for Drinking Water Quality

GB 15979-2024 Hygienic requirements for disposable sanitary products

GB 28232 Hygiene requirements for ozone sterilizers

GB 28234 Hygienic requirements for acidic water electrolysis generators

GB/T 38497 Evaluation Method for Endoscope Disinfection Effect

GB 38598 General Requirements for Labeling and Instructions for Disinfection Products

WS/T 10009 Test Methods for Disinfection Products Pharmacopoeia of the People's

Republic of China

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Automated equipment for cleaning and disinfecting flexible endoscopes.

Note. Abbreviated as endoscope cleaning and disinfection machine.

3.2 Leakage test This involves checking to ensure the integrity of the endoscope's surface and channels.

3.3 Self-disinfection cycle When unloaded, the endoscope washer/disinfector itself circulates all liquids that come into contact with the water or solution used for cleaning, disinfecting, and rinsing instruments. Disinfection treatment is carried out on the system, cavity, water tank and other components.

3.4 medical detergent A formulation used to enhance the cleaning effect of water on contaminants on medical devices, instruments and other related items.