

SN

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

SN/T 0869-2017

**Determination of ascorbic acid in beverage for export
(English Translation)**

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Foreword

SN/T 1672 "Rules for the inspection of the medical equipment for import and export"

is divided into 8 parts.

- Part 1.General requirements;
- Part 2.General spiral computed tomography scanner;
- Part 3.Transcranial Doppler blood flow analyzer;
- Part 4.B mode ultrasonic diagnostic equipment;
- Part 5.Medical diagnostic X-ray equipment;
- Part 6.Magnetic resonance imaging equipment for medical diagnosis;
- Part 7.Medical endoscope;
- Part 8.Ultrasonic diagnostic and physiotherapy equipment.

This Part is Part 7 of SN/T 1672.

This Part was drafted in accordance with the rules given in GB/T 1.1-2009.

This Part replaces SN/T 1095-2002 "For the inspection of imported medical endoscope performance".

Compared with SN/T 1095-2002, the main technical changes of this Part are as follows.

- ADD the content of Chapter 4 General requirements;

- CANCEL the concept of handover inspection in Chapter 5 Inspection in the original Rules; CHANGE the inspection mode to type test mode, conformity verification mode, sampling inspection mode;
- MODIFY the inspection content, inspection methods, technical requirements in Chapter 5 Inspection in the original Rules;
- MODIFY the single sampling scheme in the sampling inspection of the original Rules 5.4 to special inspection level S-1.

Please note that some contents of this document may involve patents. The issuing agency of this document does not assume the responsibility for identifying these patents.

This Part was proposed by AND shall be under the jurisdiction of the National Certification and Accreditation Administration.

Rules for the inspection of the medical equipment for import and export - Part 7. Medical endoscope

1 Scope

This Part of SN/T 1672 stipulates the sampling, inspection, determination of inspection results for imported and exported medical endoscopes.

This Part applies to the import and export inspection of imported and exported medical endoscopes.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) is applicable to this standard.

GB/T 2828.1 Sampling procedures for inspection by attributes - Part 1. Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

GB 9706.1-2007 Medical electrical equipment - Part 1. General requirements for safety

GB 9706.19-2000 Medical electrical equipment - Part 2. Particular requirements for

the safety of endoscopic equipment

GB 11244 General requirements for the medical endoscope and endoscope accessories

YY 0068.1 Medical Endoscopes - Rigid Endoscope - Part 1.Optical properties and test methods

YY 0068.2-2008 Medical endoscopes - Rigid endoscope - Part 2.Mechanical properties and test methods

YY 0505 Medical electrical equipment - Part 1-2.General requirements for safety - Collateral standard. Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2.2001, IDT)

YY 1028-2008 Upper gastro intestinal fiberscope

4.1 Safety requirements

The safety requirements of medical endoscopes shall comply with the provisions of GB 9706.1-2007, GB 9706.19-2000, GB 11244.The differences in the countries (regions) of use shall be considered when applicable.

4.2 Electromagnetic compatibility requirements

The electromagnetic compatibility requirements of medical endoscopes shall meet the provisions of YY 0505; the differences in the countries (regions) of use shall be considered when applicable.

4.3 Other requirements

When applicable, it shall also comply with the relevant technical requirements of the countries (regions) of use for environmental protection, energy efficiency, performance, etc. of medical endoscopes.

5.1 Selection of inspection and supervision mode

The inspection of imported and exported medical endoscopes can be carried out according to relevant national provisions, selecting the mode of type test, mode of sampling inspection, mode of compliance verification in accordance with the specific

circumstances.

5.2 Inspection method

The inspection methods under different inspection and supervision modes are.

- a) Mode of type test. Type test and unpacking inspection;
- b) Mode of sampling inspection. Batch sampling or batch-by-batch sampling inspection;
- c) Mode of compliance verification. Certificate inspection and unpacking inspection.

5.3.1 Situations to be carried out

Type test shall be carried out in any of the following situations.

- a) When the product is exported for the first time;
- b) When production is resumed after suspension for more than half a year;
- c) When changes in design, process or materials may affect its performance;
- d) When the supervisory department proposes to conduct tests.

5.3.2 Sampling

A certain number of prototypes are randomly selected from the type-finalized products in accordance with the relevant standards.

5.3.3.1 Safety testing

All applicable items shall be tested in accordance with GB 9706.1-2007, GB 9706.19-2000, GB 11244.

5.3.3.2 Electromagnetic compatibility inspection

All applicable items shall be tested in accordance with YY 0505.

5.3.3.3 Performance testing

All applicable items shall be tested in accordance with GB 11244, YY 0068.1, YY 0068.2-2008, YY 1028-2008.