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

GB/T 35512-2017

**Characterization and identification for closures of butyl rubber
(English Translation)**

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Foreword

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

This standard uses the redrafted law to amend the use of ISO 8871-2:2003 "parenteral medical devices with elastic parts Part 2. Identification and Features "and Amendment No. Amd.1.2005 (E).

This standard and ISO 8871-2:2003 technical differences are as follows.

--- On the scope of this standard made a technical differences with the adjustment, the adjustment of the situation focused on the first chapter "range", the specific Adjust as follows.

- ISO 8871-2:2003 in "This standard specifies the identification of butyl rubber stopper to ensure that this standard the product is different from other existing products. This standard specifies the physical and chemical test determination of the basic characteristics of cork, in production the product supply process serves as the basis for an agreement between the manufacturer and the user about the consistency of the product. Depending on the type of stopper and use, choose the test method. This standard does not provide butyl rubber stopper for other medical requirements, these requirements can be seen Product standards. "Amend to read" This standard specifies the most basic characteristics of butyl rubber stopper and identification. This standard is not provided Other requirements of butyl rubber stopper see the corresponding product standards ";

- added "This standard applies to butyl rubber as the main material made of medicinal stopper";

--- On the normative references, this standard made a technical difference with the

adjustment to adapt to China's technical conditions. Adjust the situation Concentration reflected in the second chapter "Normative references", the specific adjustments are as follows.

- GB/T 4498.1-2013 modified to adopt international standards instead of ISO 247:1990;
- Equivalent to the use of international standards GB/T 533-2008 instead of ISO 2781:1988;
- GB/T 31063-2014 modified to adopt international standards instead of ISO 8871-1:2003;
- increase the reference GB/T 6682-2008;

--- On the test, because the content of 3.1 "General Provisions" of ISO 8871-2:2003 is not related to the standard, so delete the "General 3.1" 3.2 ~ 3.12 adjusted to 3.1 ~ 3.11 (see Chapter 3);

--- Reagents, in order to clearly define the requirements of purified water, the 5.1 revised to "the reagents used should be of analytical grade, after distillation or Other suitable methods of preparation of purified water conductivity should not exceed 3.0μS/cm, other indicators should be consistent with GB/T 6682-2008 in the first and second level "(see 5.1).

This standard made the following editorial changes.

--- On the name, the standard name was changed to "butyl rubber stopper characteristics and identification";

--- On the appendix, in order to facilitate the use of the standard, will modify the single Appendix H is adjusted to Appendix B, ISO 8871-2:2003 appendix B ~ Appendix G is adjusted to Appendix C ~ Appendix H.

This standard proposed by the China Petroleum and Chemical Industry Federation.

This standard by the National Rubber and Rubber Products Standardization Technical Committee (SAC/TC35) centralized.

This standard was drafted unit. National Rubber and Rubber Products Quality Supervision and Inspection Center, Shenzhen Medical Device Testing Center, Shanghai Quality Supervision and Inspection Technology Research Institute, Jiangyin Exit Inspection and Quarantine, the National Latex Product Quality Supervision and Inspection Center, Guangdong Kaiwei Detection Technology Unit Co., Ltd., China National Chemical Zhuzhou Rubber Research Institute Co., Ltd..

1 Scope

This standard specifies the most basic characteristics of butyl rubber stopper and identification. This standard does not provide for the other requirements of butyl rubber stopper to see the phase should the product standards.

This standard applies to butyl rubber as the main material made of medical stopper

(hereinafter referred to as "stopper").

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version applies to this article Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 533-2008 Determination of the density of vulcanized rubber or thermoplastic rubber (ISO 2781:2007, IDT) GB/T 4498.1-2013 Determination of rubber ash - Part 1. Horse Boiler Method (ISO 247:2006, MOD) GB/T 6031-1998 Determination of vulcanized rubber or thermoplastic rubber hardness (10 ~ 100IRHD) (idtISO 48.1994) GB/T 6682-2008 analytical laboratory water specifications and test methods (ISO 3696:1987, MOD) GB/T 31063-2014 Butyl rubber medical stopper high pressure water extract (ISO 8871-1:2003, MOD)

3.1 Hardness

Should be measured according to the provisions of GB/T 6031-1998 hardness.

3.2 Density

Should be GB/T 533-2008 Method A Determination of density.

3.3 Ash

Should be GB/T 4498.1-2013 method A determination of the bottle stopper after burning of inorganic residues.

3.4 Infrared spectroscopy

Infrared spectroscopy (Py-IR) is the simplest method of analysis of corks, including pyrolysis infrared spectroscopy (Py-IR) and surface decaying Infrared spectroscopy (ATR-IR).

Appendix A is pyrolytic infrared spectroscopy, Appendix B is surface decay total reflection infrared spectroscopy. The measured infrared spectra should be compared with the control

Comparison of the spectra.

In actual operation, pyrolysis of infrared spectroscopy, the sample preparation takes a long time, the other need to be careful handling of harmful gases and oils.

In contrast, when attenuated total reflectance infrared spectroscopy is used, preparation of the sample is simple and does not require preparation.

3.5 Compression set

Compression set refers to the permanent deformation of the specimen after constant compression deformation at a certain temperature and time.

Test methods refer to Appendix C.