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

GB/T 30917-2014

**Determination of nitrosamines migrating from natural rubber
latex condoms**

天然胶乳橡胶避孕套中可迁移亚硝胺的测定

(English Translation)

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Foreword

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

This standard uses the translation method identical with the international standard ISO 29941:2010 "Condoms natural rubber latex condoms can migrate Asia Nitramine determination. " Correspondence between the consistency of the standards of international documents and normative references of the following documents.

GB/T 6682-2008 analytical laboratory use specifications and test methods (ISO 3696. 1987, MOD) GB 7544-2009 natural latex rubber condoms technical requirements and test methods (ISO 4074:2002, IDT) GB/T 27025-2008 testing and calibration laboratories General requirements (ISO/IEC 17025:2005, IDT) this standard made the following editorial changes.

--- Chapter 5 of the warnings "Warning. N- nitrosamines may be harmful to human health, the experiment should strictly abide by relevant occupational health and safety standards "on the standards front;

--- The example Imperial 6.13 inches. "" "In terms of the International System of Units millimeters" mm ".

The standard proposed by China Petroleum and Chemical Industry Association.

This standard by the National Rubber and rubber products latex products Standardization Technical Committee Technical Committee (SAC/TC35/SC4) Centralized.

Drafting of this standard. Shenzhen Medical Device Testing Center, the National Population and Family Planning Commission Quality Monitoring Center, State of latex Product Quality Supervision and Inspection Center, China Zhuzhou Chemical Industry Research and Design Institute of rubber, and rubber products National Quality Supervision and Inspection Center, Shanghai Quality and Technical Supervision and Inspection Institute, Wuhan Jissbon Health Products Co., Ansell Health Products Co., on Haiming Bang rubber Products Co., Ltd., Shanghai Industrial Co., Ltd. according to time, Guangzhou Daming

United Rubber Products Co., Ltd.

1 Scope

This standard specifies the natural rubber latex condom Test Method N- nitrosamines can be migrated.

Although no other products such as cervical cap, IUD, condom female condom made of synthetic material and be released prior to this standard A demonstration, but this method is also applicable to these products.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

ISO 3696 for analytical laboratory use specifications and test methods
(Waterforanalyticallaboratoryuse-Specification andtestmethods) ISO 4074 natural latex rubber condoms technical requirements and test methods
(Naturallatexrubbercondoms-Require-mentsandtestmethods) ISO/IEC 17025 General requirements for testing and calibration laboratories
(Generalrequirementsforthecompetenceof testingandcalibrationlaboratories)

3 Terms and Definitions

The following terms and definitions apply to this document.

Condom

Consumers worn on the penis for sexual intercourse contraception and prevention of sexually transmitted diseases medical devices.

NOTE: If consumers depending on the shape and packaging of certain instruments regarded as condoms, then according to the purpose of this standard, which is regarded as condoms.

Principle 4

Water extraction samples N- nitrosamines, concentrated extract using chemiluminescence detector by gas chromatography (GC) determination of concentrate the N- nitrosamine content. Experiments at no volatile N- nitrosamines environment.

Samples extracted out of N- nitrosamine content is expressed per gram (ng/g) with ng.

5 Reagents and materials

Warning. N- nitrosamines susceptible to ultraviolet photolysis, in the preparation of standard solutions of these substances should be avoided during exposure to sunlight or Fluorescent lighting. Application of aluminum foil to protect the standard solution, transfer solution, with water and stored in the dark 5 °C or less.