ICS 11.200
CCS C 63

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 7544-2019

Natural rubber latex male condoms - Requirements and test methods

Issued on: October 18, 2019 **Implemented on: September 1, 2020**

Issued by: State Administration for Market Regulation, China National Standardization Administration

Table of Contents

Foreword

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

This standard replaces GB/T 7544-2009 "Technical requirements and test methods for natural latex rubber condoms", and GB/T 7544-

Compared with.2009, the main technical changes except editorial changes are as follows.

--- Change the standard name to "Technical Requirements and Test Methods for Natural Rubber Latex Male Condoms";

--- In the scope of "this standard specifies the manufacture of natural latex, providing consumers with contraception and helping to prevent sexually transmitted diseases

The minimum technical requirements and test methods for condoms. "Modified to" This standard specifies the technical requirements for natural rubber latex male condoms

Seek test methods. (see Chapter 1, Chapter 1 of the.2009 edition);

--- Normative references added "ISO 10993-1 Medical Device Biology Evaluation Part 1. Risk Management Process

Evaluation and testing, ISO 10993-5 Biological evaluation of medical devices - Part 5. In vitro cytotoxicity test, ISO 10993-

10 Medical Device Biology Evaluation Part 10. Stimulation and Delayed Hypersensitivity Test, ISO 15223-2 Medical Device

Symbols for the labeling, marking and provision of information for medical devices - Part 2. Formulation, selection and confirmation of symbols,

ISO /IEC 17025 Test and Calibration Laboratory Capability Approval Guidelines, removes "EN980 for medical device labels

Graphical symbols" (see Chapter 2, Chapter 2 of the.2009 edition);

--- Removed the note for the 3.8 batch (see 3.8 of the.2009 edition);

--- Removed the 3.10 batch inspection (see 3.10 of the.2009 edition);

--- Added the terms and definitions of "3.14 production date" and "3.15 visible defects (not holes and tears)" (see 3.14,

3.15);

--- Removed the content of c) in the quality assurance (see Chapter 4 of the.2009 edition);

--- Added "Chapter 5 Batch" (see Chapter 5);

--- Added "Chapter 6 Biocompatibility" (see Chapter 6);

--- Added "Chapter 7 Microbial Contamination" (see Chapter 7);

--- Added "Chapter 8 Product Declaration" (see Chapter 8);

--- Revised the width of the provisions (see 9.3.2,.2009 version 5.3.2);

--- Revised the thickness requirements (see 9.3.3, 5.3.3 of the.2009 edition);

--- Revised the blast volume and pressure regulations (see Chapter 10, Chapter 6 of the.2009 edition);

---Modified the contents of the "General Provisions" (see 11.1, 7.1 of the.2009 edition);

--- Modified the "minimum stability requirements" (see 11.2, 7.2 of the.2009 edition);

--- Added "The pinhole test can also be performed using the method specified in ASTM D3492 [8]. For the middle width less than 45.0 mm

And/or condoms that do not include the seminal vesicle portion less than 160 mm in length cannot be considered to meet this standard. These condoms

See Appendix P for the pinhole test method. The sale of these products should be determined by the regulatory authorities or certification bodies. " (see section 12)

Chapter, Chapter 8 of the.2009 edition);

---Modified package integrity (see Chapter 14, Chapter 10 of the.2009 edition);

---Modified the contents of the package (see 15.1, 11.1 of the.2009 edition);

--- Added "General Provisions" (see 15.2.1);

---Modified the contents of the symbol (see 15.2.2, 11.2.1 of the.2009 edition);

---Modified the contents of a single package (see 15.2.3, 11.2.2 of the.2009 version);

---Modified the contents of "General Provisions a), d), f), j)" in "Consumer Packaging", adding "k), l), m), n)" (see 15.2.4.1,.2009) Year edition

11.2.3.1);

--- Removed the "sign of the super condom" (see 11.2.3.2 of the.2009 edition);

---Modified the "Additional Description of Consumer Packaging" (see 15.2.4.2, 11.2.4 of the.2009 edition);

---Added the "condoms sold in non-consumer packaging" (see 15.2.5);

---Modified the contents of the "Test Report" (see Chapter 16, Chapter 12 of the.2009 edition);

--- Revised the contents of Appendix A (see Appendix A.1, A.2, Table A.1, Appendix A.1, A.2, Table A.1 of the.2009 edition);

--- Added in Table B.1 "Inspection level and receiving quality of individual packages, lubricant content, thickness with visible seal openings

Limit" (see Appendix B);

--- Revised the contents of Appendix C and added the "Surfactant Aqueous Solution Method" (see Appendix C.3, Appendix C of the.2009 edition);

--- Revised the contents of Appendix F, adding the "thickness method to determine the thickness of condoms" (see Appendix F.3, Appendix F of the.2009 edition);

--- Added the informational appendix G, and added the corresponding strains of the Chinese Pharmacopoeia to the G.4.3 strains (see Appendix G);

--- Revised the contents of Appendix H, [see Appendix H.2.1c), H.2.1d), H.2.2, H.3.5, Appendix G.2.1c of the.2009 edition,

G.2.1d), G.2.2, G.3.5];

--- Revised the contents of Appendix I (see Appendix I.2.1, I.4.3, I.5, Appendix H.2, H.4.3 of the.2009 edition);

--- Added "the calculation formula and result representation of the tensile strength of condom test piece" in Appendix J (see Appendix J.5.2, J.6);

---Modified the contents of Appendix K (see Appendix K, Appendix J of the.2009 edition);

---Modified the contents of Appendix L (see Appendix L, Appendix K of the.2009 edition);

--- Added "Check individual packaging and record any visible sealing openings" in the test procedure for the Appendix M pinhole test (see attached)

Record M.2.3.1, M.3.3.1);

--- Amend Appendix M to "record visible defects in condoms. broken, missing or severely deformed crimps and film severely bonded" to

"Record condoms with visible defects (see 3.15) except for pinholes and tears" (see appendix M.2.3.4, M.3.3.5,.2009 edition)

L.2.3.3, L.3.3.4);

--- Modify the contents of M.2.3.6 and M.3.3.7 in Appendix M (see Appendix M.2.3.6, M.3.3.7,.2009 edition of L.2.3.5,

L.3.3.7);

--- Revised the contents of Appendix N (see Appendix N.1, N.2.5, N.2.7,.2009 edition of M.1, M.2.3, M.2.6, M.2.8);

--- Appendix P deleted the informative appendix "Description" and added "Proposals for condom testing beyond the size specified in this standard" (see attached

Record P, Appendix P of the.2009 edition.

This standard uses the translation method equivalent to ISO 4074.2015 "Technical requirements and test methods for natural rubber latex male condoms".

The documents of our country that have a consistent correspondence with the international documents referenced in this standard are as follows.

--- GB/T 2828.1-2012 Procedures for the enumeration of samplings - Part 1. Sweeping batch-by-batch inspections by the acceptance quality limit (AQL)

Sample plan (ISO 2859-1.1999, IDT)

--- GB/T 16886.1-2011 Biological evaluation of medical devices - Part 1. Evaluation and testing in the process of risk management

(ISO 10993-1.2009, IDT)

--- GB/T 16886.5-2017 Biological evaluation of medical devices - Part 5. In vitro cytotoxicity test (ISO 10993-5.

2009, IDT)

--- GB/T 16886.10-2017 Medical Device Biology Evaluation Part 10. Stimulation and Skin Sensitization Test (ISO 10993-

10.2010, IDT)

---GB/T 27025-2008 General requirements for testing and calibration laboratory capabilities (ISO /IEC 17025.2005, IDT)

---YY/T 0466.1-2016 Symbols for medical devices used for labeling, marking and providing information on medical devices - Part 1.

Requirements (ISO 15223-1.2012, IDT)