



PSB Singapore

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ISO 4074:2014 Standard Update

Date: 03 Nov 2014

Overview



1 Background

2 Update of ISO 4074:2014

3 Other standards for condoms



- ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies)
- The committee responsible for ISO 4074 is ISO/TC 157, non-systemic contraceptives and STI barrier prophylactics
- This second edition (ISO 4074:2014) cancels and replaces the first edition (ISO 4074:2002), which has been technically revised. It also incorporates the Technical Corrigenda ISO 4074:2002/Cor1:2003 and ISO 4074:2002/Cor2:2008
- Condoms might be subject to specific local requirements as required by national regulatory bodies in addition to those specified in ISO 4074:2014

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Update of ISO 4074:2014

Some of the modifications are as follows:

- Maximum lot size has been limited to 500 000 pcs
- Biocompatibility assessment, ISO 10993-1, have been added
- Recommended the manufacturers establish procedure for the periodic monitoring of microbial contamination
- Requirement for extra strength condoms have been deleted. Manufacturers to justify any additional claims made for their products
- Oven conditioning has been deleted. A minimum airburst volume of 28.0dm³ has been introduced for condoms with width greater than 65.0mm
- A limit has been introduced for the number of individual containers with visibly open seals
- Amendments have been made to the methods for determining the shelf life
- Thickness's test procedure and requirement is specified in standard
- Revisions have been made to labelling requirements including the additional information supplied with the condom

* The slide did not include all the modifications. For more details, please refer to ISO 4074:2014 standard



Update of ISO 4074:2014

Additional requirement in labelling and packaging (all the labelling and packaging requirements in ISO 4074:2002 still applied)

- Symbol shall meet the requirements in ISO 15223. Symbol used on the outside of the consumer packaging should be explained inside of the leaflet

Individual container

- Any additional marking required by local regulations

Consumer package

- Symbol may used for store the condom in a cool dry place
- A statement that Condom is made of natural rubber latex, which might cause allergic reactions including anaphylactic shock. Symbol accepted
- For condoms intended for distribution within the European Union, the CE mark
- A statement that the condom is for single use only. Symbol accepted
- A statement to read the instructions for use. Symbol accepted



Additional information

-Instruction for use of the condom

- The need to stop and check if the user feels the condom slipping off or tightening excessively onto the penis because this might lead to breakage
- Advice to seek medical assistance as soon as possible, at least within 72 h should a condom leak or burst during use
- Advice that if the individual container is obviously damaged to discard that condom and use a new one from an undamaged package
- An explanation of any symbol used on the packaging
- A statement that the condom is made of natural rubber latex, which might cause allergic reactions including anaphylactic shock if symbol used on the packaging
- The date of issue or the date of latest revision of the instructions for use
- For condoms intended for distribution within the EU, the CE mark

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Other standards for condoms



ISO 23409: 2011 Male condom- Requirements and test method for condom made from synthetic materials

NZS 7160: 1998 Polyurethane condom

ASTM D3492: 2003 Rubber contraceptives (Male condoms)

ASTM D6324: 2011 Male condom made from polyurethane condom

ISO 25841: 2011 Female condoms- Requirements and test methods

End of Presentation



Have a question?

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Thank you for your attention.