



ISO 4074:2014 Standard Update

Date: 03 Nov 2014

Overview





1 Background

2 Update of ISO 4074:2014

3 Other standards for condoms

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Background



- 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

Slide 5 **TÜV**°

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

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Update of ISO 4074:2014



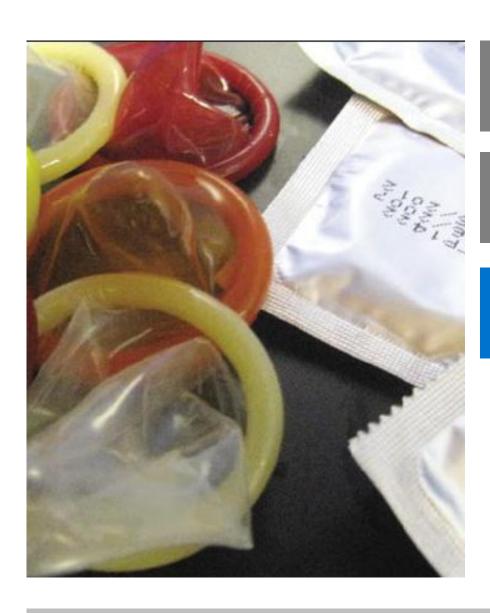
Additional information

- -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

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End of Presentation





Have a question?

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Thank you for your attention.

Slide 10 TUV®