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

*Préservatifs — Dosage des nitrosamines migrant des préservatifs
en latex de caoutchouc naturel*



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Foreword

(ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 29941 was prepared by Technical Committee ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

Condoms — Determination of nitrosamines migrating from natural rubber latex condoms

1 Scope

This International Standard specifies a test method to determine the release of *N*-nitrosamines from condoms made from natural rubber latex.

The method can also be used for other products such as probe covers, prophylactic dams, female condoms and condoms made from synthetic materials, although there was no experience of testing such products at the time of publication of this International Standard.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 4074, *Natural rubber latex condoms — Requirements and test methods*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definition

For the purposes of this document, the following terms and definitions apply.

3.1

condom

medical device used by consumers, which is intended to cover and be retained on the penis during sexual activity, for purposes of contraception and prevention of sexually transmitted infections

NOTE If a consumer could responsibly consider a device to be a condom (due to its shape, packaging, etc.), it is considered a condom for the purpose of this International Standard.

4 Principle

WARNING — Owing to their toxicity, *N*-nitrosamines can be detrimental to human health. The testing laboratories should take special care to observe the occupational health and safety standards.

N-nitrosamines are extracted into water. After having been concentrated, the water is tested for its *N*-nitrosamine content by means of gas chromatography (GC) using a chemiluminescence detector. The test is performed in an environment that is free of volatile *N*-nitrosamines.

The released *N*-nitrosamines are given in nanograms per grams (ng/g) of the sample.