Draft Indian Standard

Female condoms - Requirements and test methods

ICS NO.11.200

Obstetric and Gynecological Instruments and Appliances Sectional Committee, MHD 03

National Forward:
(Formal Clause will be added later)

This Draft Indian Standard which is identical with ISO 25841:2011 ‘Female condoms - Requirements and test methods’ issued by the International Organization for Standardization (ISO) will adopted by the Bureau of Indian Standards on the recommendation of the Obstetric and Gynecological Instruments and Appliances Sectional Committee, MHD 03 and approval of the Medical Equipment and Hospital Planning Department

A female condom is a sheath that completely lines the vaginal canal and is designated to be retained in the vagina during sexual intercourse and after withdrawal of the penis to prevent pregnancy and transmission of sexually transmitted infections (STIs).

A female condom is distinguished from a male condom in that it is retained in the vagina after withdrawal of the penis. The external components of the device can provide some coverage to the external female genitalia. Non-porous, intact, polymer films can be effective barriers to human immunodeficiency virus (HIV). Other infectious agents responsible for the contraceptive purposes and in the prevention of STI transmission. To be effective, it is essential that female condoms completely line the vaginal canal, be free from holes and defects, have adequate physical properties so as not to break during use, are correctly package to protect them during storage and are correctly labeled to facilitate their use.

To be safe, it is essential that the female condom and any lubricant, additive, dressing, individual packing material or power applied to it neither contain nor liberate substances in amounts that are toxic, sensitizing, locally irritating or otherwise harmful under normal conditions of storage or use.

Female condoms are non-sterile medical devices, but manufacturers are advised to take appropriate precautions to minimize microbiological contamination of the product during manufacture and packing. To ensure high quality products, it is essential that female condom be designed and produced under a good quality management system. Reference can be made, for example, to ISO 9000, ISO 9001, ISO 9004, ISO 13485 and ISO 14971. To estimate the shelf-life of any new or modified female condom, manufacturers conduct stability tests before the product is placed on the market. This ensures that manufacturers have adequate data to support shelf-life claims and that these data are available for review by regulatory authorities, test laboratories and purchasers. They are also initiated, but not necessarily completed, prior to placing the product on the market.
Because female condoms are a relatively new class of devices and designs of female condoms vary considerably, clinical investigations in humans are necessary to continue to build evidence of safety and efficacy. These investigations enable an assessment of the overall performance of internal and external retention features, failure modes, safety and effectiveness of female condoms. This International Standard represents minimal requirements and test methods and acknowledges that new designs can require further due rigour of retention and other features as well as additional definition of specifications and test methods by the manufacturer.

The text of the ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in the Indian Standards. Attention is particularly drawn to the following:

- Wherever the word 'International Standard' appear referring to this standard, they should be read as Indian Standard
- Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker

Cross References
In this adopted standard, reference appears to certain International Standards for which Indian standard also exist. The corresponding Indian Standard which is to be substituted in their place are listed below along with their degree of equivalence the editions indicated:

<table>
<thead>
<tr>
<th>International Standards</th>
<th>Corresponding Indian Standard</th>
<th>Degree of Equivalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 4074, Natural rubber latex condoms- Requirements and test methods</td>
<td>IS/ISO 4074:2002, Natural rubber latex condoms- Requirements and test methods</td>
<td>Identical</td>
</tr>
<tr>
<td>ISO 13485, medical devices- Quality management systems- Requirements for regulatory purposes</td>
<td>IS/ISO 13485:2003 medical devices- Quality management systems- Requirements for regulatory purposes</td>
<td>Identical</td>
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</tbody>
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'The technical committee responsible for the preparation of this standard has reviewed the provision of the following ISO standards and has decided that they are acceptable for use in conjunction with this standard'
ISO 2859-1999, Sampling procedures for inspection by attributes- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
ISO 10993-5, Biological evaluation of medical devices- Part:5 Tests for in vitro cytotoxicity
ISO 10993-10, Biological evaluation of medical devices- Part 10: Tests for irritation and skin Sensitization
ISO 10993-11, Biological evaluations of medical devices- Part:11: Tests for systemic toxicity
ISO 14155(all parts), Clinical investigation of medical device for human subjects
ISO 14971, Medical devices-Application of risk management to medical devices
ISO 15223(all parts),Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied

For the purpose of deciding whether a particular requirement of this standard is complied with, the final valve, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2: 1960 ‘Rules for rounding off numerical values (revised). The number of signified places retained in the rounded off value should be the same as that of the specified value in this standard.

Note: The technical content of the drafts is not available on website. For details please contact:

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