

---

---

## Female condoms — Requirements and test methods

*Préservatifs féminins — Exigences et méthodes d'essai*



This document is a preview generated by EBS



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Ch. de Blandonnet 8 • CP 401  
CH-1214 Vernier, Geneva, Switzerland  
Tel. +41 22 749 01 11  
Fax +41 22 749 09 47  
copyright@iso.org  
www.iso.org

# Contents

Page

<b>Foreword</b>	<b>v</b>
<b>Introduction</b>	<b>vii</b>
<b>1 Scope</b>	<b>1</b>
<b>2 Normative references</b>	<b>1</b>
<b>3 Terms and definitions</b>	<b>1</b>
<b>4 Quality verification</b>	<b>5</b>
<b>5 Lot size</b>	<b>6</b>
<b>6 Design</b>	<b>6</b>
6.1 General	6
6.2 Product insertion feature	6
6.3 Retention features	7
6.4 Lubrication	7
6.5 Dimensions	8
6.5.1 Length	8
6.5.2 Width	8
6.5.3 Thickness	8
6.6 Risk assessment	8
<b>7 Barrier properties</b>	<b>9</b>
<b>8 Biocompatibility</b>	<b>9</b>
<b>9 Clinical (human use) investigations</b>	<b>9</b>
<b>10 Microbial contamination</b>	<b>10</b>
<b>11 Bursting volume and pressure</b>	<b>11</b>
11.1 Minimum values	11
11.2 Sampling and requirements	11
<b>12 Tests for stability and shelf life</b>	<b>12</b>
12.1 General	12
12.2 Procedure for determining shelf life by real-time stability studies	12
12.3 Procedure for estimating shelf life based upon accelerated stability studies	12
<b>13 Freedom from holes</b>	<b>13</b>
<b>14 Visible defects</b>	<b>13</b>
<b>15 Packaging and labelling</b>	<b>13</b>
15.1 Individual container integrity	13
15.2 Packaging	13
15.3 Labelling	14
15.3.1 Symbols	14
15.3.2 Individual containers	14
15.3.3 Consumer packages	14
15.3.4 Additional information for the consumer	15
15.3.5 Female condoms not distributed in consumer packages	16
15.4 Inspection	16
<b>16 Data sheets</b>	<b>16</b>
<b>Annex A (normative) Sampling plans intended for assessing conformity of a continuing series of lots of sufficient number to allow the switching rules to be applied</b>	<b>18</b>
<b>Annex B (informative) Sampling plans intended for assessing conformity of isolated lots</b>	<b>19</b>
<b>Annex C (normative) Determination of lubricant mass for individual female condom containers</b>	<b>20</b>

<b>Annex D (normative) Determination of female condom length</b>	<b>22</b>
<b>Annex E (normative) Determination of female condom width</b>	<b>23</b>
<b>Annex F (normative) Determination of female condom thickness</b>	<b>24</b>
<b>Annex G (normative) Testing for female condom individual container integrity</b>	<b>26</b>
<b>Annex H (normative) Determination of barrier properties using the bacteriophage method</b>	<b>28</b>
<b>Annex I (informative) Determination of microbial contamination</b>	<b>33</b>
<b>Annex J (normative) Determination of bursting volume and bursting pressure</b>	<b>38</b>
<b>Annex K (normative) Testing for holes</b>	<b>40</b>
<b>Annex L (normative) Determination of shelf life by real-time stability studies</b>	<b>48</b>
<b>Annex M (informative) Guidance on conducting and analysing accelerated ageing studies</b>	<b>50</b>
<b>Bibliography</b>	<b>53</b>

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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

This third edition cancels and replaces the second edition (ISO 25841:2014) which has been technically revised.

The modifications are as follows:

- clinical failure mode definitions have been harmonized with ISO 29943-2;
- tolerances have been specified for the amount of lubricant applied to the female condom and the length, width and sheath thickness of the female condom. These tolerances are to be applied to the nominal values specified by the manufacturers for these design features;
- manufacturers are required to specify female condom width and thickness at three locations along the length of the female condom sheath;
- manufacturers are required to identify specifications and test methods as appropriate to verify the design and to ensure the quality and consistency of components and materials used for the retention features and any insertion feature used with the female condom;
- manufacturers are recommended to establish procedures for the periodic monitoring of microbial contamination (bioburden) as part of their quality management system including requirements for the absence of specific pathogens and limits for total viable counts on finished female condoms; methods of determining bioburden levels on female condoms are given in [Annex I](#);
- detailed changes have been made to the test methods for determining freedom from holes and airburst properties to improve the reproducibility of female condom testing between laboratories and accommodate female condoms made from a wider range of sheath materials including sheaths made from natural rubber latex;
- a greater degree of harmonization with ISO 4074 has been achieved for common requirements and definitions;

- for female condoms with sheaths made from natural rubber latex, reference is included in the procedures for estimating provisional shelflives from accelerated stability studies given in ISO 4074;
- the maximum lot size for female condoms has been limited to 500 000;
- labelling requirements have been revised and updated.

## Introduction

A female condom is a sheath that completely lines the vaginal canal and is designed 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 component of the device can provide some coverage to the external female genitalia. Nonporous, intact, polymer films can be effective barriers to human immunodeficiency virus (HIV), other infectious agents responsible for the transmission of STIs and spermatozoa. Female condoms made from polymer films that are free from holes and defects, have adequate physical properties so as not to break during use, are correctly packaged to protect them during storage and are correctly labelled to facilitate their correct use, can be effective for contraceptive purposes and in the prevention of sexually transmitted infections (STIs).

To be safe, it is essential that the female condom and any lubricant, additive, dressing, individual packaging material or powder 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 packaging. To ensure high quality products, it is essential that female condoms be designed and produced under a good quality management system. Reference can be made, for example, to ISO 9000, ISO 9004, ISO 9001, ISO 13485 and ISO 14971. To estimate the shelf life of any new or modified female condom, the manufacturer conducts 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 intended to limit the need for third parties to conduct long-term stability studies. Real-time shelf-life studies are also initiated, but not necessarily completed, prior to placing the product on the market.

Because female condoms are a relatively new class of device 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 document 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.

All of these issues are addressed in this document.





# Female condoms — Requirements and test methods

## 1 Scope

This document specifies the minimum requirements and test methods for female condoms that are supplied to consumers for contraceptive purposes and for assisting in the prevention of sexually transmitted infections (STIs).

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 2859-1:1999, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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, labelling and information to be supplied*

ISO 29943-2, *Female condoms — Guidance on the design, execution, analysis and interpretation of clinical failure mode studies*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 2859-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

### 3.1 General terms

#### 3.1.1

#### acceptable quality limit

#### AQL

quality level that is the worst tolerable process average when a continuing series of *lots* (3.1.9) is submitted for acceptance sampling

[SOURCE: ISO 2859-1:1999, 3.1.26]