

This is a preview of "ISO 25841:2014". [Click here to purchase the full version from the ANSI store.](#)

Second edition  
2014-01-15

---

---

## Female condoms — Requirements and test methods

*Préservatifs féminins — Exigences et méthodes d'essai*



Reference number  
ISO 25841:2014(E)

© ISO 2014

This is a preview of "ISO 25841:2014". [Click here to purchase the full version from the ANSI store.](#)



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2014

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  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

This is a preview of "ISO 25841:2014". [Click here to purchase the full version from the ANSI store.](#)

## Contents

	Page
<b>Foreword</b> .....	<b>v</b>
<b>Introduction</b> .....	<b>vi</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>3</b>
<b>5 Design</b> .....	<b>4</b>
5.1 General.....	4
5.2 Product insertion feature.....	4
5.3 Retention features.....	5
5.4 Lubrication.....	5
5.5 Dimensions.....	5
5.6 Risk assessment.....	6
<b>6 Barrier properties</b> .....	<b>6</b>
<b>7 Biocompatibility</b> .....	<b>7</b>
<b>8 Clinical (human use) investigations</b> .....	<b>7</b>
<b>9 Bursting volume and pressure</b> .....	<b>8</b>
9.1 Minimum values.....	8
9.2 Sampling and requirements.....	9
<b>10 Tests for stability and shelf-life</b> .....	<b>9</b>
10.1 General.....	9
10.2 Procedure for determining shelf-life by real-time stability studies.....	9
10.3 Procedure for estimating shelf-life based upon accelerated stability studies.....	9
<b>11 Freedom from holes</b> .....	<b>10</b>
<b>12 Visible defects</b> .....	<b>10</b>
<b>13 Packaging and labelling</b> .....	<b>10</b>
13.1 Package integrity.....	10
13.2 Packaging.....	10
13.3 Labelling.....	10
13.4 Inspection.....	12
<b>14 Data sheets</b> .....	<b>13</b>
<b>Annex A (normative) Sampling plans intended for assessing compliance of a continuing series of lots of sufficient number to allow the switching rules to be applied</b> .....	<b>14</b>
<b>Annex B (informative) Sampling plans intended for assessing compliance of isolated lots</b> .....	<b>15</b>
<b>Annex C (normative) Determination of lubricant mass for individual female condom containers</b>	<b>16</b>
<b>Annex D (normative) Determination of female condom length</b> .....	<b>18</b>
<b>Annex E (normative) Determination of female condom width</b> .....	<b>19</b>
<b>Annex F (normative) Determination of female condom thickness</b> .....	<b>20</b>
<b>Annex G (normative) Testing for female condom package integrity</b> .....	<b>21</b>
<b>Annex H (normative) Determination of barrier properties using the bacteriophage method</b> .....	<b>23</b>
<b>Annex I (normative) Determination of bursting volume and bursting pressure</b> .....	<b>28</b>
<b>Annex J (normative) Testing for holes</b> .....	<b>30</b>
<b>Annex K (normative) Determination of shelf-life by real-time stability studies</b> .....	<b>36</b>

This is a preview of "ISO 25841:2014". [Click here to purchase the full version from the ANSI store.](#)

<b>Annex L (informative) Guidance on conducting and analysing accelerated ageing studies</b> .....	<b>38</b>
<b>Bibliography</b> .....	<b>41</b>

This is a preview of "ISO 25841:2014". [Click here to purchase the full version from the ANSI store.](#)

## 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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 157, *Non-systemic contraceptives and STI barrier prophylactics*.

This second edition cancels and replaces the first edition (ISO 25841:2011), which has been technically revised.

## Introduction

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 component 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), to other infectious agents responsible for the transmission of STIs, and to spermatozoa. Female condoms made from polymer films can be effective for 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 packaged to protect them during storage, and are correctly labelled to facilitate their use.

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 manufacturing 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 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 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 in 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.

All these issues are addressed in this International Standard.