
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 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
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Quality verification	3
5 Design	4
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
6 Barrier properties	6
7 Biocompatibility	7
8 Clinical (human use) investigations	7
9 Bursting volume and pressure	8
9.1 Minimum values	8
9.2 Sampling and requirements	9
10 Tests for stability and shelf-life	9
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
11 Freedom from holes	10
12 Visible defects	10
13 Packaging and labelling	10
13.1 Package integrity	10
13.2 Packaging	10
13.3 Labelling	10
13.4 Inspection	12
14 Data sheets	13
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	14
Annex B (informative) Sampling plans intended for assessing compliance of isolated lots	15
Annex C (normative) Determination of lubricant mass for individual female condom containers	16
Annex D (normative) Determination of female condom length	18
Annex E (normative) Determination of female condom width	19
Annex F (normative) Determination of female condom thickness	20
Annex G (normative) Testing for female condom package integrity	21
Annex H (normative) Determination of barrier properties using the bacteriophage method	23
Annex I (normative) Determination of bursting volume and bursting pressure	28
Annex J (normative) Testing for holes	30
Annex K (normative) Determination of shelf-life by real-time stability studies	36

Annex L (informative) Guidance on conducting and analysing accelerated ageing studies	38
Bibliography	41

This document is a preview generated by EVS

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).

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).

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.

Female condoms — Requirements and test methods

1 Scope

This International Standard specifies the minimum requirements and test methods for female condoms, which are supplied to consumers for contraceptive purposes, assisting in the prevention of sexually transmitted infections.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 14155 (all parts), *Clinical investigation of medical devices 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, labelling and information to be supplied*

3 Terms and definitions

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

3.1

acceptance quality limit

AQL

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

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

3.2

consumer package

package intended for distribution to a consumer, containing one or more individual container(s) of female condoms