Annex 5

WHO/UNFPA female condom generic specification

Contents

Abbreviations

AQL	acceptance quality limit
CFU	colony-forming unit
ISO	International Organization for Standardization
ISO/TC 157	ISO Technical Committee 157 for non-systemic contraceptives and STI barrier prophylactics
ppb	parts per billion
STED	summary of technical documentation
STI	sexually transmitted infection
TC	Technical Committee
UNFPA	United Nations Population Fund
WHO	World Health Organization

1. Introduction

This annex contains the World Health Organization (WHO)/United Nations Population Fund (UNFPA) specification for female condoms that is suitable for the bulk procurement of female condoms for use in social marketing, public sector programmes for family planning and the prevention of sexually transmitted infections.

Whereas a standard usually specifies the minimum requirements for the key properties that determine the safety and effectiveness of a product, a specification is a statement of the buyer's requirements and covers all the attributes and features of the product. Some of these requirements, such as packaging and labelling, may be unique to the buyer and not specified in the International Organization for Standardization (ISO) standard ISO 25841 (*1*).

The WHO/UNFPA specification is based on the performance requirements for female condoms specified in the international standard ISO 25841: Female condoms – Requirements and test methods (*1*). This standard, which was developed by the ISO Technical Committee 157 for non-systemic contraceptives and sexually transmitted infection (STI) barrier prophylactics (ISO/TC 157), was first published in July 2011. The standard has subsequently been updated to reflect the introduction of new types of female condom designs and changes in the availability of control condoms for conducting clinical studies. This updated standard was published as ISO 25481:2017. An amendment to the standard, ISO 25841:2017/Amd 1:2020, was published in 2020. The amendment includes verification procedures for assessing the effectiveness of

the test procedures for package integrity and freedom from holes. The current edition of the standard at the date of publication of this specification is ISO 25841:2017+A1:2020.

Throughout this specification reference to ISO 25841 (*1*) will refer to the latest edition of the standard. No significant changes to ISO 25841 (*1*) are expected until at least 2025.

Many potential designs of female condom are possible, each with its own set of design parameters and specifications. A wide range of materials can also be used to make female condoms. It is therefore not possible to establish a set of performance requirements for female condoms in the same way as it is for male latex condoms. Certain performance properties, such as burst volume and pressure, will depend upon the materials used and the design of the condom. These properties will therefore vary with condom type and design. Other performance properties, such as acceptance limits for freedom from holes, are independent of the materials and designs used. Specific limits can be set for these requirements. Whenever possible, specific limits have been set in this specification.

Female condoms also have a number of essential features that are not found in male condoms. In general terms, female condoms usually have the following components:

- a sheath that lines the vagina and may extend to cover or partially cover the external genitalia;
- an external retention feature that prevents the condom from being pushed into the vagina – commonly this is a ring or frame;
- an internal retention feature that retains the condom within the vagina and permits safe withdrawal of the penis after use – examples include rings, foam sponge devices and mucoadhesive tabs;
- a product insertion feature that facilitates insertion of the condom into the vagina. The internal retention feature may also serve this function.

For the reasons given above, it is not possible to determine the safety, efficacy and acceptability of a specific type of female condom based on its design and the materials used. Instead, it is necessary to conduct clinical investigations in humans to confirm the safety, efficacy and acceptability of any new female condom design. These investigations enable an assessment to be made of the overall performance of internal and external retention features, failure modes, safety and effectiveness of female condoms.

ISO 25841 (*1*) specifies the essential performance and safety requirements that female condoms are expected to meet and the test methods that are used

to assess compliance with these requirements. It is based on extensive research and an ongoing consultation process involving leading experts in all aspects of female condom manufacturing, research and use from around the world.

Each design of the female condom will have unique features that also may need to be agreed upon between the buyer and manufacturer. The buyer's specification must be a detailed and unambiguous statement of the buyer's requirements, describing how those requirements can be measured and assessed. The specification is generally attached to the bidding documents and forms, which are part of the supply contract. It is premature to develop a design-based specification for the public sector procurement of female condoms. Many different designs of the product are possible, each having its own unique features and specification. As a result, it has been decided to detail the scientific and technical requirements manufacturers must meet for the product to be approved for public sector distribution. These requirements incorporate the design and performance requirements of ISO 25841 (*1*).

This specification covers the generic requirements for female condoms and is largely performance based. For this reason, it is known as the *WHO/UNFPA female condom generic specification*. The *WHO/UNFPA female condom generic specification* has been developed by consensus and is based on available evidence, the details of which are catalogued in a technical basis paper. This generic specification describes the general, design, performance and packaging requirements for the product and the methods of verification. Female condoms are made and tested in lots. A lot is a collection of female condoms of the same design, colour, shape, size and formulation manufactured at essentially the same time using the same process, same specification of raw materials, common equipment, same lubricant and any other additive or dressing, and the same packaging materials. Further information about lots is given in Table A5.1.

The requirements have been divided into four categories, as follows.

- **General requirements** specify the clinical performance requirements of the product; the methods to be used by the manufacturer to set the product specifications for airburst properties; and the safety of constituent materials and other characteristics, such as shelf-life. These requirements and properties should not vary from lot to lot and therefore do not need testing on a regular basis. The general requirements are listed in subsection 3.1 of this specification.
- **Performance requirements** specify the essential performance attributes of the condoms. These must be tested on a lot-by-lot basis since the quality of these attributes may vary due to the manufacturing process. Laboratory tests are conducted to ensure that the condom and the individual containers comply with the specification. Performance requirements detailed in this specification

should not be changed. The performance requirements are listed in subsection 3.2 of this specification.

- **Design requirements** are concerned with the acceptability of the product to the end user. They are listed in subsection 3.3 of this specification. Some of these properties may be varied within certain limits to meet specific programmatic requirements by agreement with the manufacturer. Unlike the situation with male condoms, however, varying a design requirement might affect the clinical effectiveness of the female condom. Since the performance and acceptability of female condoms are established by clinical investigation, the potential impact of any change must be considered carefully. Such changes are therefore not generally feasible and users should choose from amongst the approved available designs. For each design requirement, there is a means of verification.
- **Packaging requirements** are listed in subsection 3.4 of this specification. If appropriate, purchasers may specify requirements depending upon the target population. When selecting packaging, manufacturers should consider the needs of disabled users. If consumer packaging is required, it is important to include detailed instructions in the specification and to discuss the design requirements with the manufacturer.

The *WHO/UNFPA female condom generic specification* and the WHO/UNFPA Prequalification Programme guidance are designed to ensure that a quality-assured product is purchased and distributed to the end user. This WHO/UNFPA specification should not be considered or used as a standard for regulatory purposes. For regulatory purposes, the applicable standard is ISO 25841 (*1*) or the relevant local standard, depending on the country.

2. Glossary

The definitions given below apply to the terms used in this specification. They have been aligned as much as possible with the terminology in related WHO guidelines and good practices and included in the *WHO Quality Assurance of Medicines Terminology Database: list of terms and related guideline*,[7] but may have different meanings in other contexts.

acceptance quality limit (AQL). The quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance

[7] https://www.who.int/publications/m/item/quality-assurance-of-medicines-terminology-database.

sampling (ISO 2859-1). *Note*: Manufacturers should be consistently achieving a process average that is better than the AQL.

aseptic technique. Precautionary measures taken to prevent external contamination of materials, samples and culture media, employed during testing.

batch. Sometimes used in place of "lot" (see definition of lot; WHO recommends that "lot" be used when referring to condoms). The term can also refer to a homogeneous quantity of latex that has been compounded and is ready for dipping, from which several lots will be made, or to a quantity of individual raw materials.

bioburden. The population of microorganisms on a raw material, a component, a product, packaging or equipment.

bioluminescence. Light emitted when bacterial adenosine triphosphate reacts with firefly luciferin and luciferase. Bioluminescence tests are designed to measure the amount of light produced, which will be related to the number of microorganisms present in the sample.

CE mark. On condom packaging, a mark certifying that the product conforms to the essential requirements of European Medical Device Regulation (EU) 2017/745.

colony-forming unit (CFU). An estimate of the number of viable microorganisms per unit measured.

compliance testing. A regime of testing to verify that a lot complies with the specification.

consumer pack. A wallet or carton into which one or more individual containers are inserted for marketing purposes.

design requirements. Characteristics of the condom that are specified according to the buyer's requirements.

expiry date. The date by which the product is no longer considered acceptable for use.

exterior shipping carton. The container into which a number of inner boxes are packed.

forecast. An assessment of the future requirements of a programme, based on historical trends, research or feedback from fieldworkers on current needs.

general requirements. The general quality characteristics of condoms that are verified before supply commences and that are not expected to vary from lot to lot.

good manufacturing practice (GMP). A code of practice aimed at ensuring that the product is consistently manufactured to the required standard.

inner box. A box used to contain a convenient number of condoms in individual containers or consumer packs. Inner boxes will typically be presented as dispenser boxes containing 100 condoms.

inspection level. The degree of examination of the lot, as specified in ISO 2859-1. The higher the inspection level, the more samples will be tested, and hence the lower the risk of faulty products reaching the end user.

length. The length of the condom measured from the open end to the tip, excluding any reservoir.

lot. A quantity of condoms of a single grade, class, size and composition, manufactured under essentially the same conditions. With certain exceptions, all the condoms constituting a lot will have identical formulation (the same dimensions, colour, shape and surface texture), be manufactured on the same production line and be vulcanized under the same conditions.

lot number or code. A unique identifying alphanumeric code assigned to a lot.

Lowry method (modified). A method for determining the water-extractable protein levels in latex products.

national regulatory authority. A regulatory body with authority in a specific country to control the importation and distribution of medical products (see "regulatory authority").

non-visible hole. A hole in a female condom that is not visible under normal or corrected vision but is detected by the water leakage test specified in ISO 25841.

performance requirements. The critical tests of quality that all lots must pass to provide adequate consumer protection.

prequalification. The steps taken by the buyer to verify a manufacturer's suitability to provide condoms of the required quality. The WHO/UNFPA Prequalification Programme includes the periodic assessment of manufacturing dossiers, testing of samples and factory inspection.

preshipment compliance testing. A regimen of compliance tests conducted before a shipment leaves the supplier's factory.

process average. The long-term average percentage of non-complying condoms calculated separately for each attribute. Ideally, the process average for a specific attribute should be less than half the specified acceptance quality limit.

regulatory authority. A national or international body set up to oversee the safety, efficacy and quality of medical devices, including condoms, imported and distributed within a country or region.

rejection number. The minimum number of non-compliers (failures) in a test sample that will cause a lot to be rejected.

reservoir. A narrow portion of the condom at the closed end, designed to contain ejaculate. The reservoir is sometimes called the teat.

sampling plan. A specific plan that indicates the number of units (condoms) from each lot that are to be inspected (sample size) and the associated criteria for determining the acceptability of the lot (acceptance and rejection numbers).

shelf-life. The period of time after manufacture during which the product is considered acceptable for use.

specification. A detailed statement of a product's requirements as established by the buyer. Usually, a specification is based on an established standard.

standard. A detailed statement of the minimum acceptance requirements, as established by a national or international regulatory authority.

surrogate virus. A virus that is safer and easier to handle and can be used as a substitute for a pathogenic virus.

visible hole. A hole or tear in a female condom that is visible under normal or corrected vision before the condom is filled with water during the test for freedom from holes specified in ISO 25841.

viscosity. A fluid's resistance to flow.

3. WHO/UNFPA specification

3.1 General requirements

General requirements include the selection and safety of materials used to manufacture the condom and any insertion and retention devices. Manufacturers shall include, in their summary of technical documentation (STED), documentary evidence to confirm that the condoms comply with the requirements listed in Tables A5.1 to A5.5. Verification of conformance with

these requirements is assessed during prequalification and in response to any purchaser's doubts about whether or not the product complies with the *WHO/UNFPA female condom generic specification*.

Manufacturers are also required to include data in their STEDs supporting the shelf-life claims made for the product. Female condoms must comply with the performance requirements specified in subsection 3.2 of this *WHO/UNFPA female condom generic specification* throughout the stated shelf-life of the condom. Manufacturers must determine the shelf-life with real-time studies conducted at (30^{+5}_{-2}) °C. Pending the outcome of real-time studies, manufacturers may use appropriate accelerated studies to estimate a provisional shelf-life. The basis used to estimate the provisional shelf-life from the accelerated data must be explained in the product dossier and the appropriate validation data must be included.

Table A5.1
General requirements
(to be included in the STED and verified during prequalification)

Requirement	Further information
Clinical investigation report	Copies of clinical investigation reports shall be made available for review and included in the product dossier. The reports shall clearly identify the product variant to which they relate. Any changes made to the product since the clinical investigation was completed shall be documented. If a comparative clinical investigation against a marketed female condom has been conducted, the reports shall clearly identify the marketed female condom, including its manufacturer, the date of manufacture (if known) and the expiry date of the samples used in the study. The report shall include the test results for the condoms used in the trial, including burst test results.
Specification for minimum burst pressure and volume	Copies of reports relating to the setting of minimum burst pressure and volume specifications shall be made available and included in the product dossier. Reports shall include the original burst data on the lots of condoms used in the clinical investigations and details of how the minimum limits for burst pressure and volume were established. If the burst requirements are not based on the lots of condoms used in the clinical investigations, then a full justification is required to establish equivalence between the condom lots used to set the specification and those used in the clinical evaluation.

Table A5.1 *continued*

Requirement	Further information
Lot definition	A lot is a collection of condoms of the same design, colour, shape, size and formulation. A lot must be manufactured at essentially the same time, using the same process, same specification of raw materials, common equipment, and the same lubricant and any other additive or dressing, and must be packed in the same type of individual container, using the same packaging materials. All condoms comprising a lot will: • have an identical formulation; • have the same design, dimensions, colour, shape and surface texture; • be manufactured on the same production line; • be vulcanized under identical conditions; • be in the same packaging; • have the same lubricant; • have the same date of expiry printed on the package. Lot sizes over 500 000 are not permitted.
Materials	The condoms, retention features and any other components, such as insertion features, shall be made of suitable materials, as specified by the manufacturer. If significant changes are made to the grade or type of materials used, then the manufacturer may be required to repeat one or more of the safety, clinical and stability assessments of the product. Full details of the materials shall be given, including, if appropriate, polymer and copolymer compositions. Additional information about the material used for the sheath shall be given, including its key physical properties (tensile strength and modulus). For thermoplastic elastomers, the molecular weight and molecular weight distribution shall also be given.
Barrier properties	The barrier properties of the female condom shall be established by viral penetration studies using a suitable surrogate virus, for example bacteriophage phi X174. When tested in accordance with the method given in ISO 25841 (*1*), the volume of virus-containing medium penetrating the condom shall not exceed twice the limit of detection of the test for at least 80% of the condoms tested. A marketed male latex condom that complies with the requirements of ISO 4074 (*2*) may be used as a control in the study.

Table A5.1 *continued*

Requirement	Further information
Barrier properties *continued*	For condoms made from natural rubber latex with a sheath that has a minimum thickness of 0.055 millimetres (mm) and is made using conventional latex dipping processes, an exception from barrier testing is permissible since the barrier properties of such films in relation to viruses are well established. This exemption does not apply if the sheath is made using unusual dipping or vulcanization technology, if the sheath component or the finished condom is subjected to any subsequent treatment process other than washing, or if any additive other than the usual vulcanization ingredients and stabilizers is added to the latex. Confirmation of the viral barrier properties of the condom is normally completed prior to the submission for regulatory approval for the product. If any changes are made to the condom that could affect the barrier properties of the condom, for example changing the material used for the sheath component, the viral barrier test shall be repeated.
Biocompatibility	The condoms shall not liberate toxic or otherwise harmful substances in amounts that can be irritating, sensitizing or otherwise harmful to the user of the condom under normal conditions of use. Biocompatibility assessments shall be conducted on the whole condom, including the retention devices, any insertion device that might come into contact with the vagina and any lubricants and dressing materials, in accordance with ISO 10993-1 (*3*). Generally, tests for cytotoxicity shall be conducted in accordance with ISO 10993-5 (*4*) and tests for irritation and sensitization shall be conducted in accordance with ISO 10993-10 (*5*) and ISO 10993-23 (*6*). Manufacturers should choose accredited laboratories for these tests, and the results should be interpreted by an accredited toxicologist or other suitably qualified expert. In accordance with ISO 10993-1 (*3*), manufacturers may use existing data on identical materials instead of conducting their own tests. Expert reports shall be available for review. If there is a likelihood of systemic absorption of any components or residuals, further biocompatibility testing may be requested by regulatory authorities, such as testing for acute systemic toxicity in accordance with ISO 10993-11 (*7*) and testing for mutagenicity in accordance with ISO 10993-3 (*8*).

Table A5.1 *continued*

Requirement	Further information
Biocompatibility *continued*	The manufacturer shall also obtain, and make available on request from regulatory authorities, toxicity data on all the additives and residual monomers, solvents and known impurities used in the manufacture of the female condom. Suitable material safety data sheets shall be supplied on request for materials used in the manufacture of the condoms, retention features and lubricant. Regarding female condoms made from natural rubber latex, many latex products that have been established as safe, including male condoms and medical gloves, can exhibit a positive cytotoxic response when tested in accordance with ISO 10993-5 (*4*). Although any cytotoxic effect can be of concern, it is primarily an indication of potential for in vivo toxicity, and a female condom cannot necessarily be determined to be unsuitable for use based solely on cytotoxicity data. Manufacturers and purchasers are advised to confirm local requirements for safety testing with appropriate regulatory authorities in the countries in which the condoms are to be distributed.
Water-extractable protein levels	It is recommended that manufacturers of natural rubber latex-based female condoms determine the water-extractable levels of proteins in their products. The recommended level for soluble protein, as determined by the modified Lowry method, is less than 200 micrograms per gram (µg/g). Manufacturers should take steps not to exceed this level and should monitor production periodically. There is no specific standard for determining the protein levels in condoms. The methods described in ISO 12243 (*9*) , EN 455–3 (*10*) and ASTM D5712 (11) for determining the protein levels in medical gloves can be modified for condoms. Documentation recording protein levels should be available for review.
Bioburden levels	Condoms are not sterile devices but manufacturers should take steps to minimize the risk of contamination of the products with microorganisms. Some designs of female condoms may increase the risk of microbiological contamination because of the materials used and the additional manipulation required to assemble the finished device.

Table A5.1 *continued*

Requirement	Further information
Bioburden levels *continued*	It is recommended that bioburden levels on packed condoms are below 100 colony-forming units (CFU) and should not be allowed to exceed 500 CFU. There should be an absence of *Staphylococcus aureus* and Enterobacteriaceae, including *Escherichia coli*, *Pseudomonas aeruginosa* and all fungi. It is recommended that bioburden levels be determined periodically (for example, at least quarterly) by extracting the condoms with a neutralizing medium and determining the total viable aerobic count using appropriate test methods. Further information on the rationale for the bioburden limits, methods of determining bioburden levels and general guidelines on controlling bioburden contamination during manufacture is given in ISO 25841 (*1*). Confirmation that bioburden levels are below 500 CFU per condom will be assessed for lots of condoms submitted for prequalification testing.
Nitrosamines	Manufacturers of latex-based female condoms should take steps to minimize the formation of nitrosamines. This can be done by ensuring that condoms are adequately leached and washed by using minimum amounts of accelerators and by choosing accelerators, such as zinc dibutyldithiocarbamate, that have a preferred safety profile (*12*). For prequalification purposes, the manufacturer should be able to demonstrate that it is are able to achieve levels below 50 parts per billion (ppb) measured as per ISO 29941 (*13*). Levels should be monitored periodically, at least once a year, and following any significant change to the latex formulation.
Aromatic amines	Manufacturers using polyurethanes shall confirm that aromatic amines cannot be leached out of the female condom at levels that could be considered toxic.
Shelf-life	Condoms shall conform with the performance requirements of this *WHO/UNFPA female condom generic specification* throughout the stated shelf-life of the condom. The manufacturer shall determine the shelf-life based on the outcome of stability studies determined from the date of manufacture. The date of manufacture can be the date of sheath manufacture or the date of assembly and packaging of the female condom in individual sealed containers, depending on the procedures specified by the manufacturer. The date of manufacture shall not exceed six months from the date of sheath manufacture.

Table A5.1 *continued*

Requirement	Further information
Shelf-life *continued*	Unprocessed sheaths or unpackaged female condoms shall be stored under controlled conditions, as specified by the manufacturer, between sheath manufacture and packaging. Manufacturers shall have documented procedures for validating the storage conditions and maximum storage period. The stored sheaths or female condoms shall be protected from exposure to excessive temperature, light, ozone levels or anything else that could affect the shelf-life of the packaged female condoms. The claimed shelf-life shall be not less than three years and no more than five years, subject to confirmation by the appropriate stability data. For WHO/UNFPA prequalified manufacturers, the maximum period of time between sheath manufacture and assembly or packaging is six months, but manufacturers may use shelf-life data from stability studies with condoms that have been stored up to two years prior to packaging as specified by ISO 25841 (*1*) to support shelf-life claims. Manufacturers must commence real-time studies before lodging their applications for prequalification. Pending the outcome of the real-time studies, manufacturers may estimate a provisional shelf-life using an accelerated ageing study. If, at any time during the real-time studies, the manufacturer becomes aware that the shelf-life estimates made using the accelerated studies are incorrect, the manufacturer must notify UNFPA and the purchasers immediately.
Real-time stability studies	Shelf-life shall be confirmed by real-time stability studies conducted at 30 (+5/–2) °C according to the relevant clause in ISO 25841 (*1*). If the condom or any critical components, such as the retention features, are made from moisture-sensitive materials, and a moisture-impermeable packaging material is not used, then relative humidity shall be controlled at (75 ± 5) % during real-time stability studies. For confirmation, humidity control is not required when conducting stability studies on female condoms made from natural rubber latex packed in impermeable packaging.

Table A5.1 *continued*

Requirement	Further information
Real-time stability studies *continued*	Details about the methods of determining the shelf-lives of female condoms are given in ISO 25841 (*1*). If the female condom sheath is made from natural rubber latex by conventional dipping processes and the female condom is packed in an oxygen-impermeable individual container, for example, made from aluminium foil laminate, then the procedure used to determine a provisional shelf-life of natural latex male condoms described in ISO 4074 (*2*) can be used. For female condoms with sheaths made out of synthetic materials, the procedures described in ISO 11346 (Rubber, vulcanized or thermoplastic – Estimation of life-time and maximum temperature of use) (*14*) may be appropriate. The procedures used for accelerated stability studies shall be appropriate to the raw materials of the condom. The results of an accelerated ageing study, according to ISO 25841 (*1*), must be available at the time of submitting an application for prequalification and a real-time study must also be in progress.
Sampling	Condoms for stability studies shall be taken from three normal production lots. Sampling shall be done according to Annex A or Annex B (preferred) of ISO 25841 (*1*). The sample sizes from each lot should be adequate to complete all the tests specified in Annexes L and M of ISO 25841 (*1*) and include sufficient samples to permit retesting in full after at least one additional time point during the studies.
Conditioning	Samples shall be conditioned in their individual sealed containers according to the relevant annex of ISO 25841 (*1*). At the end of the incubation periods, withdraw the condoms and test for airburst properties, freedom from holes and package seal integrity.
Testing requirements	For real-time stability studies, all three lots of condoms shall conform to the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of ISO 25841 (*1*) for the full specified shelf-life of the product. For accelerated studies, suitable means of extrapolation shall be used to support the specified shelf-life.

Table A5.1 *continued*

Requirement	Further information
Stability study reports	The stability study reports should indicate the time between sheath manufacture and assembly or packaging for the lots used for the study. If a manufacturer has not recorded the required information in the stability study report, then the default position will be that the manufacturer must use the sheath manufacturing date as the date of manufacture.
Individual container	The individual container shall not adversely affect the properties of the female condom. The individual container shall be sealed and shall provide an adequate level of protection consistent with the materials used to manufacture the condom. The individual container shall not allow lubricant to leak. Individual containers for female condoms made from natural rubber latex, or other materials that can be affected by light, shall be opaque. It is unlikely that biodegradable packaging will provide sufficient product protection for female condoms made from natural rubber latex. The individual containers shall have sufficient mechanical strength to protect the condoms during shipping and storage. Purchasers may choose to specify special packaging requirements at the purchase order stage, in which case the requirements must be included in the purchase specification.

3.2 Performance requirements

The performance requirements specified here are based on the requirements in the current published edition of ISO 25841 (*1*). These requirements cannot be altered. Verification of compliance with these requirements must be done as part of the prequalification process and the lot-by-lot preshipment compliance testing of the product.

For prequalification purposes (that is, when testing fewer than five lots), the sampling plans specified in Annex B of ISO 25841 (*1*) shall be used. For lot-by-lot compliance testing (that is, when testing continuing series of lots), the sampling plans specified in Annex A of ISO 25841 (*1*) shall be used. Sample requirements for testing are summarized in Appendix 1.

Table A5.2
Performance requirements

Requirement	Further information
Bursting volume and pressure	
Sampling	In accordance with ISO 2859-1: Sampling procedures for inspection by attributes (general inspection level I) (*15*). For prequalification testing, at least code letter M as specified in Annex B of ISO 25841 (*1*) shall be used.
Testing	In accordance with the method given in the relevant annex of ISO 25841 (*1*). Condoms shall comply with the minimum burst volume and pressure requirements specified by the manufacturer, as determined according to the method described in ISO 25841 (*1*).
Requirements	The limit for nonconforming condoms is an AQL of 1.5.
Freedom from holes and visible defects, including critical visible defects in packaging	
Sampling	ISO 2859-1 general inspection level I (*15*), but at least code letter M shall be used. For prequalification testing, at least code letter N as specified in Annex B of ISO 25841 (*1*) shall be used.
Testing	Condoms shall be assessed in accordance with the method given in the relevant annex of ISO 25841 (*1*). Critical visible defects in the individual containers are also assessed at the same time using the same samples. The list of critical and non-critical visible defects for the condoms and individual containers is given in Appendix 2.
Requirements	The limits for nonconforming condoms are: • freedom from holes: AQL 0.25 • critical visible defects: AQL 0.4 • non-critical visible defects: AQL 2.5. The limit for nonconforming individual containers is an AQL of 0.4. Female condoms with non-visible holes in any position greater than 25 mm from the open end and visible holes in any position along the whole length of the sheath are considered nonconforming. Descriptions of critical visible defects and non-critical visible defects are given in Appendix 2. Exact definitions of critical and non-critical defects should be reviewed and agreed on during the contractual process.

Table A5.2 *continued*

Requirement	Further information
Package integrity (seal integrity)	
Sampling	ISO 2859-1 inspection level S-3 (*15*) . For prequalification testing, at least code letter H as specified in Annex B of ISO 25841 (*1*) shall be used.
Testing	In accordance with the method given in the relevant annex of ISO 25841 (*1*).
Requirements	The limit for nonconforming individual containers is an AQL of 2.5.

3.3 Design requirements

Since the approval of female condoms is based on a satisfactory outcome from the clinical investigation, any change in the design of the condom or the materials used requires a detailed evaluation to ensure that the safety and effectiveness are not compromised. A full risk assessment using, for example, the procedures described in ISO 14971 (*16*) shall be conducted following any significant change to the design, formulation, manufacturing process, equipment used and packaging. As a consequence of the risk assessment, further clinical investigation of the product or retesting may be required. Approval from relevant regulatory and notified bodies may be required before the changes can be implement. A prequalified manufacturer implementing such changes must inform the UNFPA Prequalification Programme about the changes.

For the design requirements listed in Table A5.3, the nominal specified requirements shall be the same as those for the samples of condoms submitted for clinical investigation. All condoms tested in the sample shall fall within the tolerances specified for the specified mean nominal value. Any variation in the specified tolerances may be acceptable at the time of prequalification, subject to a full justification for the variation and agreement with UNFPA.

Table A5.3
Design requirements

Requirement	Further information
Sampling	Unless otherwise stated, all design requirements shall be assessed using a sample size of 13 female condoms.
Requirements	Unless otherwise stated, all samples shall conform to specification.

Table A5.3 *continued*

Requirement	Further information
Essential features	
Verify by visual inspection	A female condom will normally have the following essential features: • A sheath component that lines the vagina and may extend to cover or partially cover the external genitalia. • An external retention feature to prevent the condom from being pushed into the vagina. Commonly this is a ring or a frame. • An internal retention feature that retains the condom within the vagina and permits safe withdrawal of the penis after intercourse. Examples include rings, foam sponge devices and mucoadhesive tabs. • A product insertion feature that facilitates insertion of the condom into the vagina. The internal retention feature may also serve this function.
Minimum burst properties	The minimum burst volume and pressure for the condom shall be based on results obtained by testing at least 2000 female condoms from the lot or lots used in the clinical trial (if more than one lot was used the samples shall be drawn across all lots in proportion to the size of each lot). The minimum burst pressures and volume limits shall be set at 80% of the 1.5 percentile values of the measured airburst volumes and pressures. Round the bursting volume limit to the nearest 0.1 cubic decimetre (dm^3) if the value is 14.9 dm^3 or below, and to the nearest 0.5 dm^3 if the value is greater than 14.9 dm^3. Round the bursting pressure to the nearest 0.05 kilopascal (kPa). After a period of essentially continuous production of at least 30 full-scale manufacturing lots, the limits should be re-evaluated to confirm that they are still applicable.
Requirements	All condoms in the sample shall have the essential features and components specified by the manufacturer, which shall be the same as those for the condoms used in the clinical investigation. These requirements include: • the materials used for the sheath and all retention features; • the method of manufacture of the female condom in including the sheath and the retention features; • the dimensions of the sheath and retention features; • the physical properties of the materials used for the sheath and retention features; • the type and amount of lubricant used.

Table A5.3 *continued*

Requirement	Further information
Requirements *continued*	If any of these critical design requirements are changed for any reason, a full risk assessment must be completed to demonstrate that the safety and effectiveness of the product has not been compromised. A further clinical investigation may be necessary to confirm this.
Colour	
Pigment	If any pigment is used to colour the condom, it shall be suitable for use in medical devices. Full details of any pigments used shall be supplied along with the relevant material safety data sheets.
Colour assessment	A sample of female condoms from each lot shall be inspected visually for colour (colour may be assessed on the same sample of condoms used to assess other design requirements). Reference samples or colour charts may be used to define and assess colour. Exact colour matches may not be possible.
Odour and flavour	
Verify by visual inspection and smell	The condoms shall not give off an unpleasant odour when the package is opened at any time after manufacture and during the shelf-life of the product. (Many materials, including natural rubber latex, have a characteristic odour. Often the odour tends to dissipate quickly once the package is opened. A mild odour that dissipates quickly is acceptable.) It is suggested that appropriate reference samples be retained by the testing laboratory to help resolve disputes over odour. It is recommended that the retained samples be kept for the duration of the shelf-life of the condom. Purchasers may, by agreement with the manufacturer, specify the addition of a suitable fragrance or flavour. Such fragrances and flavours must be non-toxic and non-irritant and must not adversely affect the performance and acceptability of the condom. If a fragrance or flavour is included, full details of the fragrance or flavour, including a material safety data sheet, shall be included in the STED and data sheet.

Table A5.3 *continued*

Requirement	Further information
Testing	See Appendix 3 for guidance on odour testing. If a masking agent or fragrance is used, odour testing should become part of the lot-by-lot preshipment compliance testing. Odour testing should be included in ageing studies. Evaluation of odour is inherently subjective, and a degree of tolerance is required when assessing products for conformance with the specification.
Width	
Testing	Samples from each lot shall be assessed in accordance with the method given in the relevant section of ISO 25841 (*1*). The width of a female condom is unique to each design. The manufacturer shall specify the nominal width of female condoms at each of the measurement locations given in the relevant annex of ISO 25841 (*1*). The maximum tolerance for width requirements shall be ± 2 mm around the specified width.
Length	
Testing	Samples from each lot shall be assessed in accordance with the method given in the relevant annex of ISO 25841 (*1*).
Requirements	The length of a female condom is unique to each design. The manufacturer shall specify a nominal length for the female condom consistent with the length of the female condoms used in the clinical investigation. The maximum tolerance shall be ± 5 mm if the nominal length is 150 mm or less and ± 10 mm if the nominal length is greater than 150 mm.
Thickness	
Testing	A sample from each lot shall be tested in accordance with the method given in the relevant annex of ISO 25841 (*1*). The thickness of a female condom is unique to each design. The manufacturer shall specify a nominal thickness of the female condom at each of the measurement locations specified in the relevant annex of ISO 25841 (*1*). The thickness shall be consistent with the thickness of the female condoms used in the clinical investigation. The tolerance shall be ± 0.01 mm. For female condoms made from natural rubber latex with sheath thicknesses greater than 0.1 mm, a tolerance of ± 0.015 mm shall apply.

Table A5.3 *continued*

Requirement	Further information
Quantity of lubricant including powder	
Testing	Samples from each lot shall be tested in accordance with the method given in ISO 25841 (*1*). The design of a female condom may include lubrication in any of the following forms: • lubricant preapplied directly to the female condom during packaging; • lubricant supplied in a separate container to be applied to the female condom by the user; • lubricant both preapplied to the female condom and supplied in a separate container. The type and amount of lubricant is unique to each female condom design. The manufacturer shall specify the amount of lubricant, which shall be the same as that used in the clinical investigation.
Requirements	The manufacturer shall specify the amount of lubricant, which shall be the mean amount of lubricant used in the clinical investigation. All female condoms in the sample tested shall be within ± 15% of the specified mean. Manufacturers shall specify test methods as appropriate to verify the design and to ensure the quality and consistency of the lubricant. The specification for the lubricant should include viscosity. If the lubricant is supplied separately from the female condom, then manufacturers shall provide full details on how the lubricant should be used. These details shall be consistent with the instruction given with the clinical investigation samples. The quantity of lubricant supplied in the container shall be not less than the amount supplied with the clinical investigation samples. The containers for the lubricant shall not leak. An inspection level of S-3 and an AQL of 1.5 are recommended for assessing lubricant container integrity. Consult the purchase order and specification to determine if additional packaging requirements apply to the lubricant container.

Table A5.3 *continued*

Requirement	Further information
Retention features and other additional components	
Sampling	A sample of 13 female condoms shall be tested from each lot.
Testing	The dimensions of all retention features and any other ancillary components, such as insertion features, shall be measured using the methods specified by the manufacturers. Manufacturers are required to specify mechanical properties for the retention features that are relevant to the correct function of the feature. Examples could include stiffness and elastic memory parameters for rings, resilience and recovery times for foams and adhesion properties for adhesive pads. The specification requirements shall be based on the lots used in the clinical investigation. Periodically, purchasers and other interested parties may assess the physical properties specified for the internal and external retention devices.
Requirements	The dimensions of the retention features and other ancillary components for every condom tested shall comply with those specified by the manufacturer. The specified dimensions for retention features shall be the same as those for the clinical investigation samples within a tolerance of ± 5%. The mean mechanical properties of the retention features shall be the same as those used for the clinical investigation samples within a tolerance of ± 10%. All samples tested shall comply.
Individual container markings	
Sampling	A sample of 13 individual containers and, if appropriate, 13 consumer packs shall be taken from each lot.
Testing	The individual containers are visually inspected to verify the required aspects of package marking.
Requirements	The colour, print design and identification markings, including Pantone references and font sizes, shall be as specified by the buyer and annexed to the specification for the product. All samples shall comply.

Table A5.3 *continued*

Requirement	Further information
Verified by visual inspection	The individual containers shall not adversely affect the properties of the female condom. The individual containers shall be sealed and shall provide an adequate level of protection consistent with the materials used to manufacture the condom. The individual containers shall not allow lubricant to leak. The recommended individual containers shall have sufficient mechanical strength to protect the condoms during shipping and storage.
Verified by supplier's data or independent test requirement	The lot numbers on individual containers should be printed at the time of packaging. If this is not feasible, then manufacturers shall ensure that there are adequate procedures to ensure that the correct lot number is placed on the individual containers. The individual containers shall have the following markings, which shall be clearly legible under normal and corrected vision: • the identity of the manufacturer or distributor or, if permitted by local regulations, the registered brand or trademark; • the lot number or lot identification code (printed at the time of packaging, not preprinted); • expiry date – month and year labelled expiry date in languages to be specified by the purchaser (printed at the time of packaging, not preprinted) – the year shall be written as a four-digit number and the month as a two-digit number; • instructions for use that are clearly legible in pictorial form or in languages to be specified by the purchaser (may be supplied separately if unable to print on the packaging); • the statement relating to the effectiveness of the condom, if required by the purchaser (see *Family planning: a global handbook for providers*, section 14, "Female condoms" (*17*), for information about the effectiveness of female condoms); • a warning about the risk of allergic reactions to the condom if the condom is made from natural rubber latex. Purchasers may specify the use of Braille for specific information, including the expiry date. If a separate lubricant and condom are supplied in the same package, then the expiry date shall be the shorter of the two. The expiry date shall be printed on all packages (that is, the individual condom container, the lubricant package and any outer or consumer package). All inspected individual containers and, if appropriate, consumer packs shall comply with the packaging requirements.

3.4 Packaging requirements for shipment

Inspections or verifications in this section will generally be carried out during prequalification, lot-by-lot preshipment compliance testing and periodic inspections.

Information included on all packaging shall be in the language specified by the purchaser.

Table A5.4
Packaging requirements for shipment

Requirement	Further information
Consumer packaging	No requirements for consumer packs (sometimes called wallet packs) are included in the *WHO/UNFPA female condom generic specification*. If required, the full design of the consumer pack should be specified in accordance with the requirements of the programme.
Inner boxes	The inner boxes shall be packed into plastic bags or other bags with waterproof linings, which will be placed in three-wall cartons made from weather-resistant corrugated fibreboard with a bursting test strength of no less than 1900 kPa. The inner boxes will be marked in a legible manner to facilitate identification in case of subsequent queries. The following information shall be included in the inner box marking: • A description of contents. • Lot identification number. • Month and year of manufacture (including the words "date of manufacture", "month" and "year") in languages to be specified by the purchaser. The year shall be written as a four-digit number and the month as a two-digit number. • Month and year of expiry (including the words "expiry date", "month" and "year") in languages to be specified by the purchaser. The year shall be written as a four-digit number and the month as a two-digit number. • Manufacturer's name and registered address. • Number of condoms in the box. • Instructions for storage. *Note*: all markings must be legible. Inner box markings can be specified in accordance with programme requirements.

Table A5.4 *continued*

Requirement	Further information
Interior shipping cartons	The inner boxes shall be packed into plastic bags or other bags with waterproof linings, which will be placed in three-wall cartons made from weather-resistant corrugated fibreboard with a bursting test strength of no less than 1900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps, or with water-resistant tape, 75 mm wide, applied to the full length of the centre seams and extending over the ends by not less than 75 mm. The cartons may be secured by plastic strapping in no less than two positions. Alternatively, wire-bound, cleated plywood or nailed wood boxes are acceptable when lined with a material that provides a waterproof barrier. The barrier material must be sealed at the edges with waterproof tape or adhesive, and there must be no sharp protrusions inside the boxes. In some countries, the three-wall corrugated fibreboard available is not of sufficient strength and rigidity to meet stacking requirements or to resist being cut at the corners when the plastic strapping is applied. In such cases, an inner carton of two-walled corrugated fibreboard shall be inserted into the shipping carton before packing the condoms.
Exterior shipping cartons	The exterior shipping carton, like the inner box, shall be marked with information about the contents in a clearly legible manner. Information should be printed on two adjacent sides. The information shall include: • A description of the contents. • Lot identification number. • Month and year of manufacture (including the words "date of manufacture", "month" and "year") in languages to be specified by the purchaser. The year shall be written as a four-digit number and the month as a two-digit number. • Month and year of expiry (including the words "expiry date", "month" and "year") in languages to be specified by the purchaser. The year shall be written as a four-digit number and the month as a two-digit number. • Name and address of the manufacturer or supplier. • Number of female condoms contained in the carton. • The consignee details. • Instructions for storage and handling.

Table A5.4 *continued*

Requirement	Further information
Lot traceability	Condom lots presented for inspection and acceptance must be complete and packed in their exterior shipping cartons. Provision should be made during production for sufficient additional condoms from each lot to replace those sampled for acceptance testing. Wherever practicable, lots must be shipped in their entirety and be kept whole during containerization and shipping. The manufacturer should take all reasonable steps to maintain the shipments in discrete lots as far as practicable down the distribution chain. These steps may include the use of very large letters for lot codes, colour coding and the grouping of pallets with the same lot number.

3.5 Information for the user

Table A5.5
Information for the user

Requirement	Further information
Information	If information is to be provided with the condom, in accordance with local regulations or programme requirements or specified by the purchaser, then the following instructions and information should be considered for inclusion in the inner box or the secondary or consumer carton. The language, which should be appropriate for the intended population, shall be specified by the purchaser: • how to handle the female condom carefully, including removal from the package to avoid damage to the condom by fingernails, jewellery, or other means; • how and when to insert the female condom – mention shall be made that the female condom should be inserted into the vagina before any contact occurs between the vagina and the partner's body to assist in the prevention of STIs (sexually transmitted infections) and pregnancy; • a statement instructing the user to stop and check if they feel the female condom slipping into or out of the vagina; • if the lubricant is supplied with the condom but in a separate sachet, then instructions on how to use the lubricant shall be provided along with a description of the lubricant and an expiry date;

Table A5.5 *continued*

Requirement	Further information
Information *continued*	• a statement informing the user about which type of additional lubricant can be used with that specific female condom and how the lubricant should be used; • if the female condom is made with natural rubber latex, a statement instructing the user to avoid using oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter and margarine, as these are deleterious to the integrity of the female condom; • a statement instructing the user to consult a doctor or pharmacist about the compatibility of topical medicines and other topical products that may come into contact with the female condom; • advice on seeking medical assistance as soon as possible should a female condom fail during use; • advice to discard the female condom and use a new one from an undamaged package if the individual package is obviously damaged; • advice on withdrawing the penis soon after ejaculation, leaving the female condom in place in the vagina; • instructions for withdrawal and disposal of the female condom; • a statement that the condom is for single use only and that cleaning and reuse can compromise the integrity of the device; • explanation of any symbol used on the packaging; • if a symbol for latex is used on the packaging, a statement that the female condom is made of natural rubber latex, which may cause allergic reactions, including anaphylactic shock, if the user is allergic to latex; • the date of issue or the date of latest revision of the instructions for use; • if the product is manufactured to conform to all requirements of ISO 25841, the number of the standard (that is, ISO 25841); • for female condoms intended for distribution within the European Union, the CE mark. It is recommended that the following statement relating to the safety and effectiveness of the condom be included: "When correctly used every time you have sex, female condoms reduce the risk of unintended pregnancy, HIV and some other sexually transmitted infections. Use a new condom every time you have sex and follow the instructions carefully."

References

Note: Where standards are undated the latest edition of that standard applies. All URLs accessed January 2024.

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2. ISO 4074. Natural rubber latex male condoms – Requirements and test methods (https://www.iso.org/obp/ui/#iso:std:iso:4074:ed-3:v1:en).
3. ISO 10993-1. Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (https://www.iso.org/obp/ui/#iso:std:iso:10993:-1:ed-5:v2:en).
4. ISO 10993-5. Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity (https://www.iso.org/obp/ui/#iso:std:iso:10993:-5:ed-3:v1:en).
5. ISO 10993-10. Biological evaluation of medical devices – Part 10: Tests for skin sensitization (https://www.iso.org/obp/ui/#iso:std:iso:10993:-10:ed-3:v1:en).
6. ISO 10993-23. Biological evaluation of medical devices – Part 23: Tests for irritation (https://www.iso.org/standard/74151.html).
7. ISO 10993-11. Biological evaluation of medical devices – Part 11: Tests for systemic toxicity (https://www.iso.org/obp/ui/#iso:std:iso:10993:-12:ed-4:v1:en).
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13. ISO 29941. Condoms – Determination of nitrosamines migrating from natural rubber latex condoms (https://www.iso.org/obp/ui/#iso:std:iso:29941:ed-1:v1:en).
14. ISO 11346. Rubber, vulcanized or thermoplastic – Estimation of life-time and maximum temperature of use (https://www.iso.org/obp/ui/#iso:std:iso:11346:ed-3:v1:en).
15. ISO 2859-1. Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection (https://www.iso.org/obp/ui/#iso:std:iso:2859:-1:ed-2:v1:en).
16. ISO 14971. Medical devices – Application of risk management to medical devices (https://www.iso.org/obp/ui/#iso:std:iso:14971:ed-3:v1:en).
17. Family planning: a global handbook for providers, 2022 edition (https://www.who.int/publications/i/item/9780999203705).

Appendix 1

Summary tables: prequalification and lot-by-lot testing

Tables 1 and 2 summarize the testing methods and requirements for ensuring that there are no packaging defects, general requirements, performance requirements and design requirements for prequalification and lot-by-lot compliance testing. The requirements should be assessed against those specified in the manufacturer's data sheet for the specific product.

Table 1
Summary of prequalification tests (isolated lots)

Characteristics	Sampling	Verification	Requirement
Burst volume and pressure	ISO 2859-1 Level G-I Minimum code letter L (200 samples) For prequalification testing, minimum code letter M (315 samples) shall be used	Laboratory testing Comply with manufacturer's specification	AQL 1.5
Freedom from holes	ISO 2859-1 Level G-I For prequalification testing, minimum code letter N (500 samples) shall be used	Laboratory testing	AQL 0.25
Visible defects	ISO 2859-1 For prequalification testing, minimum code letter N (500 samples) shall be used	Visual inspection	Critical defects: AQL 0.4 Non-critical defects: AQL 2.5
Visible defects: individual containers	ISO 2859-1 Level G-I For prequalification testing, minimum code letter N (500 samples) shall be used	Visual inspection	Critical defects: AQL 0.4

Table 1 *continued*

Characteristics	Sampling	Verification	Requirement
Design	13 condoms per lot	Visual inspection and measurement	Comply with manufacturer's specification All samples comply
Individual container integrity	ISO 2859-1 Special inspection level S-3 For prequalification testing, minimum code letter H (50 samples) shall be used	Laboratory testing	Laboratory testing AQL 2.5
Colour	13 condoms per lot	Visual inspection	Comply with manufacturer's specification All samples comply
Scents and flavouring	13 condoms per lot	Sensory inspection	Comply with manufacturer's specification
Width	13 condoms per lot	Laboratory testing	All samples comply
Length	13 condoms per lot	Laboratory testing	Comply with manufacturer's specification
Thickness	13 condoms per lot	Laboratory testing	Comply with manufacturer's specification All samples comply
Lubricant quantity (including powder)	13 condoms per lot	Laboratory testing	Comply with manufacturer's specification All samples comply
Retention feature properties	Special inspection level S-2	Laboratory testing	AQL 2.5

Table 1 *continued*

Characteristics	Sampling	Verification	Requirement
Odour (if necessary)	13 condoms per lot	Sensory inspection	Comply with manufacturer's specification
Inner box	ISO 2859-1 Level S-3	Visual inspection	All samples comply
Exterior shipping cartons	ISO 2859-1 Level S-2	Visual inspection	Comply with manufacturer's specification

Table 2
Summary of lot-by-lot preshipment compliance testing and requirements (continuing series of lots)

Characteristics	Sampling	Verification	Requirement
Burst volume and pressure	ISO 2859-1 Level G-I	Laboratory testing	AQL 1.5
Freedom from holes	ISO 2859-1 Level G-I Minimum code letter M	Laboratory testing	AQL 0.25
Visible defects	ISO 2859-1 Level G-I Minimum code letter M	Laboratory testing	Critical defects: AQL 0.4 Non-critical defects: AQL 2.5
Visible defects: individual containers	ISO 2859-1 Level G-I	Visual inspection	Critical defects: AQL 0.4
Individual container integrity	ISO 2859-1 Special inspection level S-3	Laboratory testing	AQL 2.5
Design	13 condoms per lot	Visual inspection	Comply with manufacturer's specification All samples comply

Table 2 *continued*

Characteristics	Sampling	Verification	Requirement
Colour	13 condoms per lot	Visual inspection	Comply with manufacturer's specification All samples comply
Scents and flavouring	13 condoms per lot	Sensory inspection	Comply with manufacturer's specification All samples comply
Width	13 condoms per lot	Laboratory testing	Comply with manufacturer's specification All samples comply
Length	13 condoms per lot	Laboratory testing	Comply with manufacturer's specification All samples comply
Thickness	13 condoms per lot	Laboratory testing	Comply with manufacturer's specification All samples comply
Lubricant quantity (including powder)	13 condoms per lot	Laboratory testing	Comply with manufacturer's specification All samples comply
Retention feature properties	Special inspection level S-2	Laboratory testing	AQL 2.5
Odour (if necessary)	13 condoms per lot	Sensory inspection	Comply with manufacturer's specification All samples comply

Table 2 *continued*

Characteristics	Sampling	Verification	Requirement
Packaging and labelling	13 condoms per lot	Visual inspection	Comply with manufacturer's specification All samples comply
Inner box	ISO 2859-1 Level S-3	Visual inspection	Comply with manufacturer's specification All samples comply
Exterior shipping cartons	ISO 2859-1 Level S-2	Visual inspection	Comply with manufacturer's specification All samples comply

Appendix 2

Workmanship and visible defects

1. Introduction

All female condoms in the sample are inspected for workmanship and visible defects as part of the freedom from holes test prior to mounting on the test equipment. The number of condoms exhibiting a visible defect is recorded and defects are classified either according to the type of defect listed below or as specified in the contract.

Visible defects are divided into (a) critical visible defects, and (b) non-critical visible defects.

The individual containers in the sample are also inspected for critical visual defects before the samples are removed for testing. Critical visible defects in the packaging that could have an adverse effect on the properties of the condom are listed in Table 1.

2. Types of visible defects in condoms

It is not possible to define all critical and non-critical visible defects, and it may be necessary to exercise some judgement about whether a particular visible defect is critical.

If the visible defect may affect the performance of the female condom, the defect is considered critical. If a defect not listed in Table 1 is considered critical by any party, the purchaser, test laboratory and manufacturer must consult with each other to agree on the classification of the defect concerned.

2.1 Critical visible defects

Critical visible defects may adversely affect the performance of the condom. Condoms with critical visible defects are therefore nonconforming.

ISO 25841 covers the most common critical visible defects. Some of the more common critical visible defects are described in Table 1.

These are evaluated by visual inspection as part of the procedure for freedom from holes testing. An acceptance quality limit (AQL) of 0.4 is applied to these defects.

Other types of critical visual defects are occasionally seen and they should be assessed for their potential effect on the performance and acceptability of the condom. If a defect can be expected to affect the performance, safety or acceptability of the condom, it should be classified as a critical defect.

Table 1
Critical visible defects: AQL of 0.4

Defect	Description
Blister or bubble	An obvious circular or teardrop-shaped thin area with a well defined border in the film (such defects may break under pressure).
Coagula (large)	For female condoms made from natural or synthetic rubber latex, rubber particles with any dimension greater than 1 mm. These may cause the condom to fail during use.
Embedded and surface particles	Any particle with any dimension of 1 mm or greater. These particles may be dirt, hair, insects, etc.
Retention features	Broken, cracked, missing, damaged or severely distorted retention features (as in ISO 25841:2011). Incomplete attachment of the sheath to the external retaining feature. Disintegrating sponge internal retention features. Presence of sharp edges on retention features that could cause discomfort or damage to the vagina or penis.
Crack marks	For female condoms made from natural or synthetic rubber latex, lines that penetrate the surface of the film, formed by shrinkage of the latex during drying. These do not include flow lines or marks from the mould.
Delamination	For female condoms made from natural or synthetic rubber latex, areas in which the individual layers of latex separate (if the condom is formed by two or more dips in the latex).
Thin areas	Small areas of the condom that are visibly thin. These can show up as bulges with well-defined edges on the freedom from holes test. Condoms that look asymmetrical when filled with water are not necessarily in this category.
Seams	For female condoms made by welding, poorly welded or creased seams that could fail during use or cause discomfort. Large lumps of material within the seam that could potentially cause discomfort or damage to the vaginal mucosa.
Pleat or crease	The film sticks to itself and the pleat or crease cannot be removed by gentle stretching of the adjacent film, and unintentional adhesion to retention features.
General	Any defect that can be seen to adversely affect the performance or safety of the product.

2.2 Non-critical visible defects

Non-critical visible defects are considered minor defects as they may not cause the female condom to fail to meet the specification. Nevertheless, they are undesirable from the user's standpoint. If non-critical visible defects are specified in a purchase specification, an AQL of 2.5 is recommended. Inspection for non-critical visible defects is conducted on the samples used for freedom from holes testing.

Depending on the requirements of the specific user population, the purchaser may wish to include in the specification specific non-critical visible defects, including the most common ones, as listed in Table 2. Detailed descriptions of the non-critical visible defects should be discussed with the manufacturer and included in the contract.

Other types of non-critical defects should be assessed to determine if they will affect the acceptability of the product.

Table 2
Non-critical visible defects: recommended AQL of 2.5

Defect	Description
Small coagula and embedded particles	Small coagula and embedded particles that are not considered to pose any risk of causing the condom to fail during use.
Faulty retention features (minor)	Uneven, partially distorted or otherwise minor defects in the internal and external retention features.

3. Imperfections

Occasionally, imperfections can be seen in female condoms that do not affect the performance or acceptability of the condom. A list of the more common imperfections that fall into this category is given in Table 3. No action should be taken when these imperfections are seen.

Table 3
Imperfections that are not regarded as defects

Phenomenon	Description
Microcoagula	For female condoms made from natural or synthetic latex, particles of rubber with dimensions less than 1 mm.
Flow lines	Lines of denser material in the film.

Table 3 *continued*

Phenomenon	Description
Distortion due to rolling at packing	Apparent variations in condom width due to stretching during rolling.
Bulges	Large bulges or distortion of the female condom during the freedom from holes test that are due to minor differences in thickness or product design (these may or may not have well defined edges).
Uneven lubricant	A portion of the sheath part of the female condom may appear dry. This can be regarded as an imperfection if it does not interfere with the insertion of the condom into the vagina.
Seam imperfections	Minor creases close to the seams that have no impact on the airburst properties of the condom.
Uneven colour	Minor streaking of the sheath or retention features and uneven colour or discoloration.

Note: Any visible hole anywhere in the female condom, including close to the external retention feature, is not acceptable. These defects are counted as holes if they can be seen before water is added to the condom, even if they are within 25 mm of the open end.

4. Packaging defects

The main packaging defects are listed in Table 4. Additional defects are sometimes detected only after shipment.

4.1 Individual containers

The requirements for individual containers are specified in Table A5.3 of the *WHO/UNFPA female condom generic specification*.

4.2 Consumer packs

No requirements for consumer packs are included in the *WHO/UNFPA female condom generic specification*. Purchasers should fully specify requirements in accordance with condom programme needs. Compliance should be assessed through visual inspection, using a sampling plan in accordance with ISO 2859-1 inspection level S-3. It is recommended that an AQL of 2.5 be applied for consumer pack requirements.

4.3 Cartons and marking

Purchasers should fully specify requirements in accordance with condom programme needs. Compliance should be assessed through visual inspection, using a sampling plan in accordance with ISO 2859-1 inspection level S-3. It is recommended that an AQL of 4.0 be applied for carton requirements.

Table 4
Packaging defects

Consumer packs	Cartons and markings
Empty or partially empty containers	Non-permanent markings
Discolouration	Empty cartons or cartons not filled to order
Delamination of the packaging film	Damaged cartons that may affect the integrity or the quality of the condoms inside
Illegible printing	Number of condoms not as specified
Missing manufacturer's name	Individual containers not as specified; packaging or packing materials not as specified, missing, damaged or non-serviceable
Incorrect or missing lot number	Illegible printing
Incorrect or missing date of manufacture	Missing manufacturer's name
Incorrect or missing expiry date	Incorrect or missing lot number
	Incorrect or missing date of manufacture
	Incorrect or missing expiry date
	Shipping cartons inadequately closed and secured
	Poor application of internal packaging and packing material; distorted intermediate packaging

Appendix 3

Guidelines on the assessment of odour and fragrances

Odour and fragrances are best assessed by a panel. There are certain guidelines that apply when assessing the odour and effectiveness of fragrances on condoms. Following these guidelines should help provide a more consistent level of odour assessment. Recommendations include the following.

- The panel should consist of between six and 10 individuals.
- Panellists should not wear perfume, smoke or be exposed to a strong odour on assessment days.
- Panellists should be trained and should undergo periodic assessments using appropriate reference odours and samples.
- Odour assessments should not be carried out in a factory or other environment in which a strong background odour may be present.
- Odour assessments should be done blind and in a random order, without the panellists being aware of the source of the samples.
- Adequate time should be allowed between samples for the panellists' olfactory sense to recover.
- To prevent fatigue, the number of samples evaluated in one session should be limited.
- An appropriate grading system should be developed to quantify the intensity, acceptability and type of odour. For example, odour intensity can be rated on a balanced scale from 0 (no perceptible odour) to 6 (extremely strong odour).
- Control samples should be included to allow comparisons to be made between different panels and different sessions.
- The time delay between opening a condom pack and smelling the condom can be critical. This time should be standardized and preferably short.

It is recommended that manufacturers retain unopened samples for reference purposes and to help resolve disputes. Retained samples should be kept for the duration of the shelf-life of the product and stored in line with the manufacturer's recommendations.