UNFPA PQ application documents

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UNFPA PQ application documents

1. Introduction
2. Documents required for PQ application
3. STED
4. Responses to Document Review comments
5. Notifying significant changes
6. Summary

2. UNFPA PQ application documents

- **PQ application Process**
- **Submission of Expression of Interest**
- **Covering letter**
- **Summary Technical Documentation and supporting documentation**
- **Product samples**
- **Responses to comments on Document review**

3. UNFPA PQ application documents - STED

STED:

- **Harmonised with Prequalification, product approval requirements, currently in practice**
- **GHTF – IMDRF**
- **Adopted to cover the requirements relevant to male latex condoms**
- **Integrated requirements of Product Dossier and Site Master File**
- **Can be extended to female condoms**

3. UNFPA PQ application documents - STED

- Document in English
- Any certificates, documents etc, which may be in any other language, authorised English translation should be attached
- Table of contents including the main section and the subsection as in the order of the this document. Pages should be consecutively numbered. The sections and subsections should be arranged in specific sequence/folders.
- Annexures should be serially numbered linking with the section/ subsection and should be referenced in the table of contents
- Electronic copy/ soft copy.

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1. Information about the product(s)

1.1. Characteristics of the product(s)

- **Widths**
- **Thickness range**
- **Lengths**
- **Shapes**
- **Textures**
- **Lubricant(s)**
- **Flavours**
- **Finishing powders**
- **Colours**
- **Other relevant information**

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1.2 Local, country and regional regulatory approvals for the products

- **A summary list and copies of relevant certificates related to the product including local product/marketing approvals, CE marking, etc.**

- **List the countries in which:**

- **The products have been registered and granted a marketing authorization;**
- **An application for marketing authorization is currently pending;**
- **Any marketing approvals that have been revoked within the last five years**

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1.3 Raw materials

List all raw materials, including lubricants.
Use the following table as an example.

Compounding

Chemical name	Brand name/manufacturer's name	function

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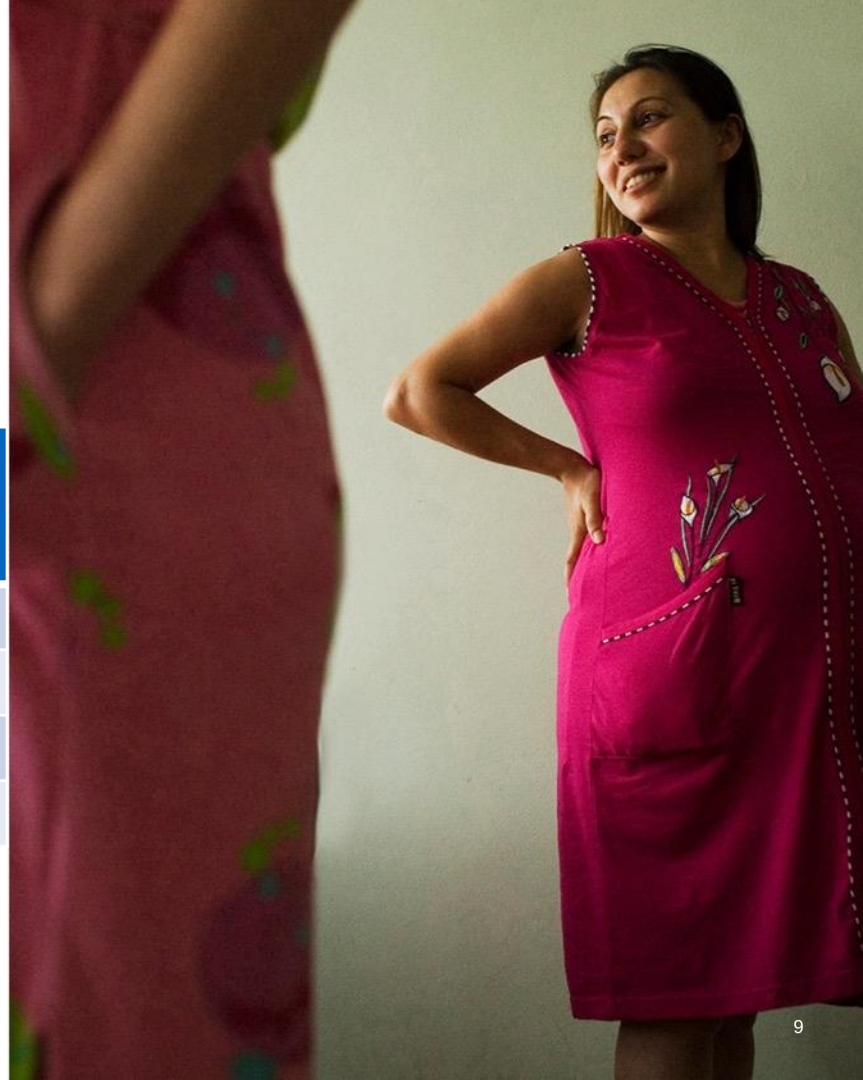
1.3 Raw materials

Others

Chemical name	Brand name/manufacturer's name	function

The role and function of any unusual chemicals should be explained and justified



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1.4 Supplier(s) of raw materials

Name, street address and country of each facility from which natural rubber latex (or prevulcanised latex) is obtained.

1.5 Specifications for the finished products

- **Do the condoms that you currently manufacture meet the requirements of *ISO 4074?***
- **Do you currently manufacture any condoms meeting the requirements of the *WHO/UNFPA Specification?***
- **Specify differences – how the compliance will be achieved**

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1.6 Evidence of compliance with WHO/UNFPA's General Requirements

- confirmation that condoms are made of natural rubber latex;
- verification that biocompatibility evaluations have been carried out in accordance with ISO10993 parts 1, 5 and 10 respectively for cytotoxicity, irritation and sensitization;
- summary reports of biocompatibility evaluations including a toxicologists' report assessing the safety of the product;

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1.6 Evidence of compliance with WHO/UNFPA's General Requirements

- confirmation that protein levels on finished products are periodically monitored and submission of summary data confirming conformity with *WHO/UNFPA* recommended limits;

- confirmation that bioburden levels on finished products are periodically monitored and submission of summary data confirming conformance with *WHO/UNFPA* recommended limits.

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2 Stability data

- **Stability data representative of all the products (including various flavours, colours, textures, etc) supporting the stated shelf-life claims.**
- **Stability reports explaining how the shelf life claims have been determined.**
- **Submitted information shall confirm compliance with the minimum stability requirements of *ISO 4074* and include data from a real-time study conducted at 30 °C (range 28 °C to 35 °C) according to *ISO 4074* supporting the claimed shelf life of the product.**

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2 Stability data

- **Manufacturers must either have completed real time stability studies for their current condom or have initiated such studies at the time of applying for prequalification. If real-time stability studies are not complete, manufacturers must have completed accelerated ageing studies conducted according to the relevant annex of *ISO 4074* to support their shelf-life claims.**

- **Procedures for conducting these studies are summarised in Chapter 2, Clause 2.1.**

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3 Labelling and additional information

Examples of the labelling that will be used for the:

- **Individual packages;**
- **Inner boxes;**
- **Exterior shipping cartons.**

All labelling and additional information, including the instructions for use, shall comply with the requirements specified in the *WHO/UNFPA Specification*.

Manufacturers that do not produce condoms to the *WHO/UNFPA Specification* at the time of prequalification may supply draft copy or print proofs for review.

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3 Labelling and additional information

- **Actual examples of printed foil should be supplied to allow assessment of the quality of the print used for LOT number, manufacturing date and expiry date (if necessary, labelling for current products that does not meet the full requirements of the *WHO/UNFPA Specification* may be supplied).**

- **Manufacturers should note that requirements for labelling and additional information may be subject to specific contractual requirements, depending upon the requirements of the purchaser.**

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4 Risk Analysis

4.1 Risk Management Plan for the Product according to *ISO 14971* and *ISO 13485*.

4.2 Risk Management Report for the product in accordance with the Risk Management Plan.

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5 Manufacturing

5.1 Manufacturing Site(s)

1. Name and exact address of the site(s) including e-mail, and 24-hour telephone numbers.

If there is more than one site listed state the operations carried out at each site.

If part finished and finished condoms are transferred between sites and if so, describe the arrangements for this process.

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5 Manufacturing

5.1 Manufacturing Site(s)

2. Brief information about the corporate structure, including information about holding or parent company, affiliates, subsidiaries and partners.

3. Total manufacturing capacity of the site(s),

- dipping capacity
- electronic testing capacity
- packaging capacity

4. Length of time manufacturing condoms at the site(s).

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5. Length of time manufacturing condoms at other sites not included in the prequalification submission.

6. What other, if any, manufacturing activities take place at the site(s).

7. Summary of the types of condoms manufactured at the site(s).

8. Outsourced activities including any manufacturing operations, testing and calibration.

9. Operations carried out at the specified site(s)

10. Location of warehouse used store raw materials, work in progress and finished condoms.

11. Interrelationship between sites, in case of multisite organizations

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5.2 Manufacturing certifications

A list and copies of all relevant certifications, including *ISO 14001*, *ISO 13485* and *ISO 9000* series if applicable.

5.3 Production

1. **Brief description of production operations and procedures, using, wherever possible, flow sheets and charts and specifying important parameters; identify equipment by type (e.g. dipping machines, electronic testing machines);**

2. **Summary of the procedures and arrangements for the handling and storage of starting materials, work in progress, packaging materials, quarantine and rejected materials, WIP and products, and finished products, including product release and storage;**

3. **Brief description of the general policy for process validation and a summary of the validation plan.**

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6 Premises and equipment

1. Simple plan or description of manufacturing areas with indication of scale (architectural or engineering drawings not required);

2. Brief description of the nature of construction of the building and finishes of floors, ceilings and walls;

3. Brief description of ventilation systems, including steps taken to prevent product contamination and excessive exposure of staff to ammonia and dust;

4. Brief description of the areas for handling compounding ingredients;

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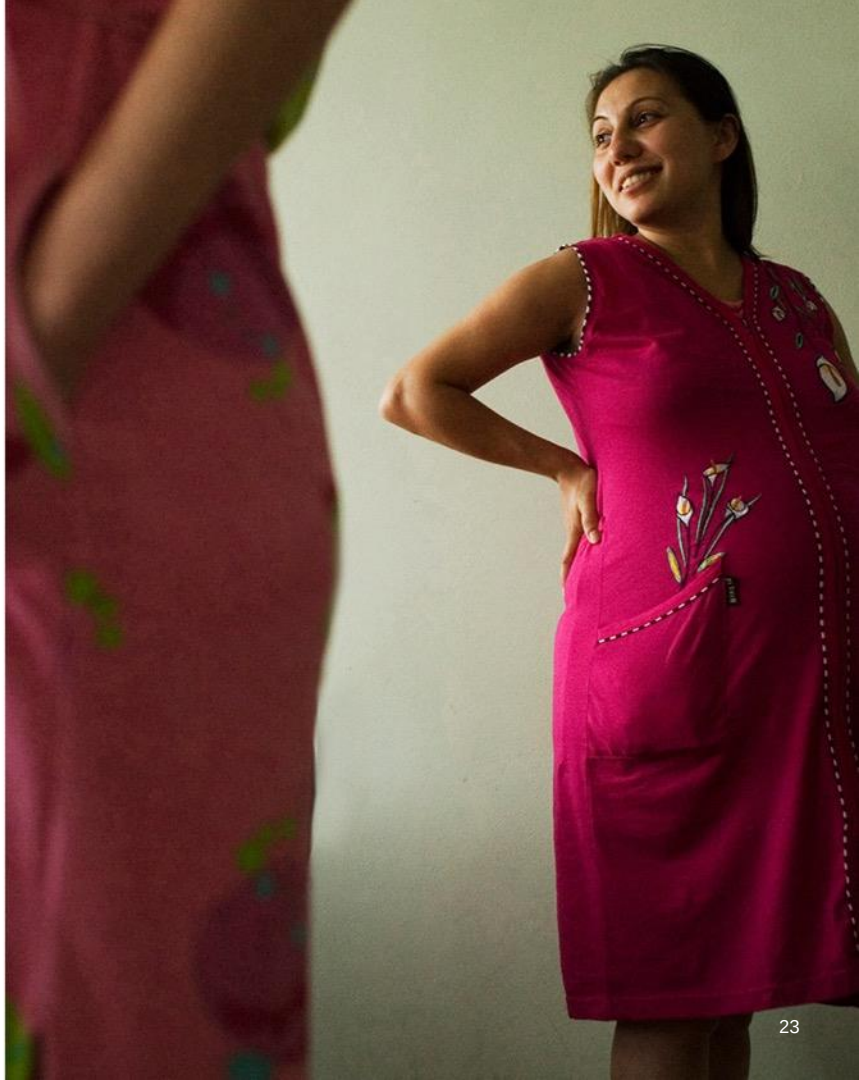
5. Description of water systems, including sanitation and effluent treatment; schematic drawings of the systems are desirable;

6. Summary of planned preventive maintenance programmes for manufacturing and testing equipment;

7. Brief description of major equipment used in production and control laboratories, including major computer systems used for production and quality control (a full list of equipment is not required);



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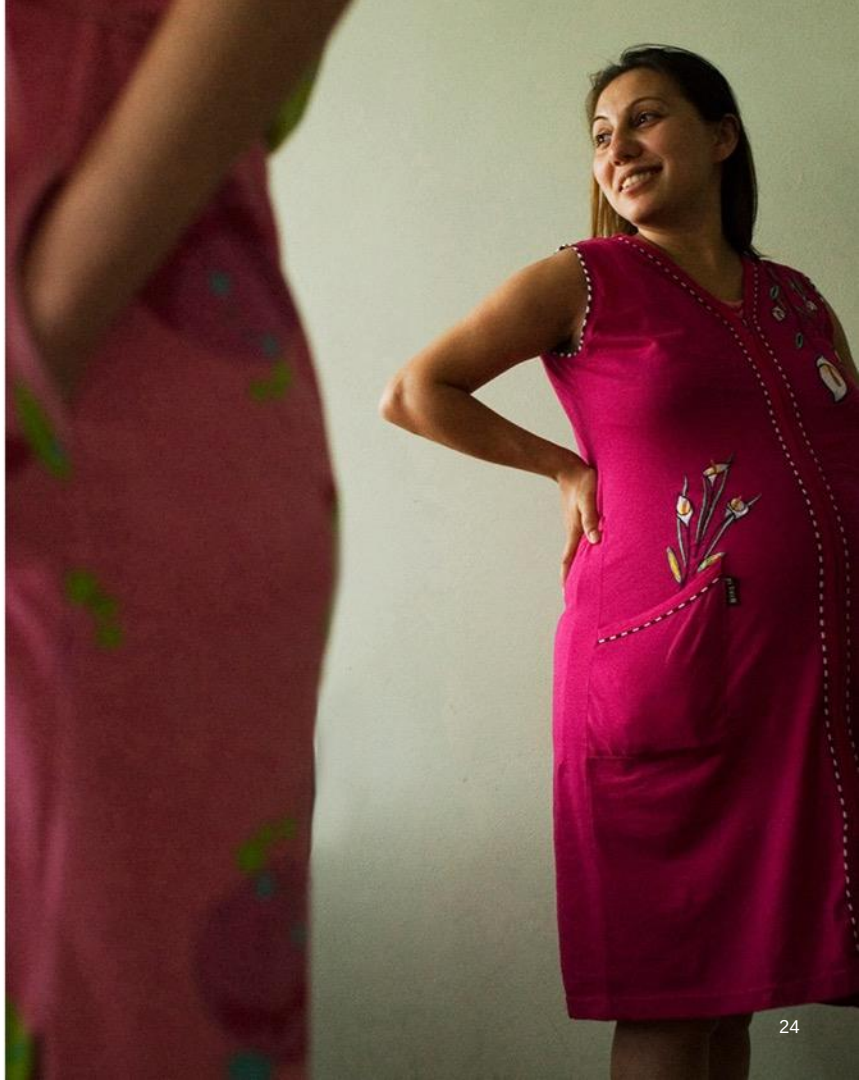
8. Description of the qualification and calibration arrangements, including the recording system, for computerized systems validation

9. Summary of the specifications and procedures for cleaning manufacturing areas and equipment;

10. Summary of the procedures for monitoring and controlling microbiological contamination in production areas and of the product, and procedures for controlling the purity of the air and water.



3. UNFPA PQ application documents - STED

7 Personnel

1. Total number of persons employed in condom manufacturing;

2. Breakdown of the numbers employed by the following categories: senior management, production management, quality assurance, quality control, maintenance, and administration;

3. Organization chart showing all management and supervisory positions, including names of senior staff,

4. The qualifications, experience and responsibilities of key personnel, senior managers, and directors, quality assurance supervisors, production manager/directors and laboratory manager/director, if appropriate;

3. UNFPA PQ application documents - STED

7 Personnel

5. Summary of policy and procedure for health requirements for personnel engaged in production;

6. Brief description of the staff training scheme and the structure and maintenance of training records;

7. Brief summary of personnel hygiene and safety requirements, including protective clothing;

8. confirmation that there is a written health and safety policy and a summary of the key components of this policy;

9. information on the use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis

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8 Quality Management System (QMS)

8.1 Documentation

Provide details of the arrangements for the preparation, revision and distribution of all necessary management system

8.2 Records

Provide details of the arrangements for safe storage, access and retrieval of records.

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8 Quality Management System (QMS)

8.3 Quality control

1. Brief details of the quality control system and of the activities of the quality control department;

2. brief details of the sampling and testing procedures for in-process testing and final product release, including pass/fail criteria. Include information about the use of control charts and other statistical process control procedures used to monitor product quality;

3. Brief details about the procedures for the calibration and maintenance of testing equipment and participation in inter-laboratory proficiency programmes.

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8.4 Management Review Meeting

Procedures and schedules for the management review meetings. Include details on how output from the management review meetings are recorded and actioned. A copy of a recent management review meeting report.

9 Distribution, complaints and product recall

1.Brief description of procedures and arrangements for LOT traceability;

2. Brief description of the arrangements for managing and recording complaints and product recalls;

3. Description of the procedures for post market surveillance

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10 Internal Audits

10.1 Procedures

Short description or a copy of the SOP for conducting internal audits system including training requirements and procedure for auditors.

10.2 Reports

A copy of a recent internal audit report.

11 Corrective and preventive action

Provide a brief description of the procedures and arrangements for identifying, reviewing and implementing corrective and preventive actions.

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Female condoms:

- **Details of Materials**
- **Clinical investigation**
- **Product specification**
- **Sketch with dimensions**
- **Finished product specification**
- **Stability data**

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TCu380 A IUDs

- Components- T frame, thread, insertion tube, insertion rod, positioning flange, individual pouch, Copper components
- Biocompatibility
- Bioburden control and terminal sterilization
- Stability studies
- In-process and finished product release tests
- Packaging and labelling

4. UNFPA PQ application documents – Responding to comments on document review

- **Review outcome: Accept/ not Accepted/ partially accepted/ comments.**
- **Response within 30 days**
- **Link the additional details submitted with the comments in the document review report and STED**
- **Suggested to keep the rounds of document review minimal to expedite further steps in PQ process.**

5. UNFPA PQ application documents – Notifying significant changes

- **The STED submitted should be continually updated**
- **Significant changes should be notified to UNFPA PQ team**
- **Guidance document in draft form in UNFPA website**
- **Change notification form**
- **Revision of STED**

6. UNFPA PQ application documents – Summary

- **Comprehensive, well arranged document**
- **Review and update details in each section whenever submitted**
- **Confirm compliance to current editions of requirements**
- **Details as recent as possible**
- **Where summaries are requested, please provide only the summary**
- **Provide additional details, in case of any deviations from the requirements**

6. UNFPA PQ application documents – Summary

- **Copies of the certificates and registrations should be current and valid**

- **In case clarification is needed, do not hesitate to contact UNFPA PQ team.**

- **Continually notify UNFPA PQ significant changes to documentation earlier submitted**

Thank you