|  |
| --- |
| WHO/UNFPA Female Condom prequalification inspection report |
| Name of Factory, Country |
| Dates of Inspection |
|  |
| **Lead Inspector: Name, Company**  **Co-Inspector: Name, Company** |
| Report Date |



**Signature of Lead-inspector**

**Report No:**

**UNFPA Release of Report**

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Inspection Report Template

(The template is a guideline, not all subsections may be relevant for the commodity inspected)

# General inspection information

## UNFPA inspection team (including inspectors, observers and translators)

## Manufacturer representatives and responsibilities

text

## Inspection programme

Text

# General company information

## Address and contact details

text

## Designs manufactured, stock levels, markets served

text

## Independent certifications

text

## Regulatory approvals

text

## Operating hours and shifts

text

## Changes since last WHO/UNFPA Prequalification inspection

text

## Points arising out of document review

text

# Human Resources

## Key personnel

## Management staff responsibilities

## Out-of-office hours responsibilities

## Prequalification focal point

## Number of and allocation of staff (permanent and contract staff)

## Staff selection and training systems

## Staff welfare

# Production capacities throughout the operation

## Number and type of machines

## Capacity, Yields

## Production capacity

## Capacity of key manufacturing stages and equipment

# Raw Materials

## Vendor evaluations including service providers, and validation acceptance and procedures

## Procedures for selection and purchase of raw materials

## Quality assurance and storage procedures

# Preparation of dispersions and compounds

# Latex pre-valcunization and maturation process and controls (where applicable)

## Process

## Adequacy of equipment

## Testing and controls

## Documentation and labelling

# Manufacturing of sheath (including assembly if applicable)

## Materials used

## Process including testing and controls

## Adequacy of equipment and staff

# Testing

# Packaging (including assembly if applicable)

# Consumer/customer packing

# Warehousing

# Distribution procedures

# Quality control plan

# Provision for storage and control of work in progress

# Outgoing product quality

# Quality system and documentation

## Document control

## Management review

## Contract Review

## Design and Development

## Identification and traceability

## Customer Complaint Analysis

## Corrective and Preventive Actions

## Change controls

## Process Validations

## Post - Market surveillance

## Environmental Control

## Control of nonconforming products –scrap security

## Internal Audits

# Risk Management Procedures

# Maintenance

# Laboratory facilities, competence and calibration

# Shelf-life stability

# Building, grounds and services

# Environmental Policy

# Prequalification independent testing

# Strengths and Weaknesses

# Summary of Recommendations

i. Major Non-conformities*[[1]](#endnote-1)*:

ii. Minor Non-conformity*[[2]](#endnote-2)*:

iii. Observations*[[3]](#endnote-3)*:

# Recommendation to UNFPA

1. An applicant that receives a major non-conformity cannot be prequalified and will require submission of corrective and preventative actions and a possible re-inspection [↑](#endnote-ref-1)
2. Minor non-conformities require corrective and preventative action to be submitted to UNFPA by the applicant in the stated period in order to achieve or maintain prequalification. If corrective and preventive actions have not been adequately addressed after two rounds of review, manufacturers will be asked to re-apply for prequalification. [↑](#endnote-ref-2)
3. Manufacturer should note item, but prequalification is not contingent upon items being addressed. [↑](#endnote-ref-3)