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| who/unfpa Male Condom prequalification inspection report |
| Name of Factory, Country |
| Dates of Inspection |
|  |
|  |
| **Report Date** |

|  |
| --- |
| **Application Number:**  **Lead-inspector:** |



**Signature of**

**Lead-inspector:**

**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:**

*a. UNFPA inspection team (including inspectors, observers and translators)*

*b. Manufacturer representatives and responsibilities*

*c. Inspection programme*

# **General company information**

*a. Address and contact details*

*b. Condom designs manufactured, stock levels, markets served*

*c. Independent certifications*

*d. Regulatory approvals*

*e. Operating hours and shifts*

*f. Changes since last WHO/UNFPA Prequalification inspection*

*g. Points arising out of document review*

# **Human Resources**

*a. Key personnel*

*b. Management staff responsibilities*

*c. Out-of-office responsibilities*

*d. Prequalification focal point*

*e. Number of and allocation of staff (permanent and contract staff)*

*f. Staff selection and training systems*

*g. Staff welfare*

# **Production capacities throughout the operation**

*a. Number and type of machines*

*b. Capacity,Yields*

*c. Production capacity*

*d. Capacity of key manufacturing stages and equipment*

# **Raw Materials**

*a. Procedures for selection and purchase of raw materials*

*b. Quality assurance and storage procedures*

*c. Vendor evaluations including service providers, and validation acceptance and procedures*

# **Preparation of dispersions and compounds**

# **Latex pre-valcunization and maturation process and controls**

*a. Process*

*b. Adequacy of equipment*

*c. Testing and controls*

*d. Documentation and labelling*

# **Dipping**

*a. Processing (washing and powdering)*

# **Electronic testing**

# **Foiling**

# **Protein Level Monitoring**

# **Bioburden Monitoring**

# **Biocompatibility Testing**

# **Consumer/customer packing**

# **Warehousing**

# **Distribution procedures**

# **Quality control plan**

# **Provision for storage and control of work in progress**

# **Outgoing product quality**

# **Quality system, Documentation and Records**

*a. Document control*

*b. Management review*

*c. Contract Review*

*d. Design and Development*

*e. Identification and traceability*

*f. Customer Complaint Analysis*

*g. Corrective and Preventive Actions*

*h. Change controls*

*i. Process Validations*

*j. Post - Market surveillance*

*k. Environmental Control*

*l. Control of nonconforming products –scrap security*

*m. Internal Audits*

# **Risk Management Procedures**

# **Maintenance**

# **Laboratory facilities, competence and calibration**

*a. Inter- Laboratory testing*

# **Shelf-life stability**

# **Building, grounds and services**

# **Environmental Policy**

# **Prequalification independent testing**

# **Strengths and Weaknesses**

# **Summary of Recommendations**

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

*ii. Minor Non-conformities[[2]](#footnote-2):*

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

# **Recommendations**

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 [↑](#footnote-ref-1)
2. Minor non-conformities require acceptance of evidence of corrective and preventive actions for 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. [↑](#footnote-ref-2)
3. Manufacturer should note item, but prequalification is not contingent upon items being addressed. [↑](#footnote-ref-3)