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| --- |
| who/unfpa Intrauterine device prequalification inspection report |
| Name of Factory, Country |
| Dates of Inspection |
|  |
| **Lead Inspector: Name, Company**  **Co-Inspector: Name, Company** |
| **Report Date** |

|  |
| --- |
| **Report Number:**  **Lead-inspector:** |



**Signature of**

**Lead-inspector:**

**UNFPA**

**Receipt:**

Contents

[1. General inspection information: 2](#_Toc378583552)

[2. General company information 2](#_Toc378583553)

[3. Human Resources 2](#_Toc378583554)

[4. Production capacities throughout the operation 2](#_Toc378583555)

[5. Raw Materials 2](#_Toc378583556)

[6. Preparation of compounded materials 3](#_Toc378583557)

[7. Moulding 3](#_Toc378583558)

[8. Assembly 3](#_Toc378583559)

[9. Provision for storage and control of work in progress 3](#_Toc378583560)

[10. Packaging 3](#_Toc378583561)

[11. Sterilization 3](#_Toc378583562)

[12. Warehousing 3](#_Toc378583563)

[13. Distribution procedures 3](#_Toc378583564)

[14. Quality control plan 3](#_Toc378583565)

[15. Outgoing product quality 3](#_Toc378583566)

[16. Quality system and documentation 3](#_Toc378583567)

[17. Risk Management Procedures 4](#_Toc378583568)

[18. Maintenance 4](#_Toc378583569)

[19. Laboratory facilities, competence and calibration 4](#_Toc378583570)

[20. Shelf-life stability 4](#_Toc378583571)

[21. Building, grounds and services 4](#_Toc378583572)

[22. Environmental Policy 4](#_Toc378583573)

[23. Prequalification independent testing 4](#_Toc378583574)

[24. Strengths and Weaknesses 4](#_Toc378583575)

[25. Summary of Recommendations 4](#_Toc378583576)

[26. Recommendation to UNFPA 4](#_Toc378583577)

**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

* 1. *Address and contact details*
  2. *Designs manufactured, stock levels, markets served*
  3. *Independent certifications*
  4. *Regulatory approvals*
  5. *Operating hours and shifts*
  6. *Changes since last WHO/UNFPA Prequalification inspection*
  7. *Points arising out of document review*

# Human Resources

* 1. *Key personnel*
  2. *Management staff responsibilities*
  3. *Out-of-office hours responsibilities*
  4. *Prequalification focal point*
  5. *Number of and allocation of staff (permanent and contract staff)*
  6. *Staff selection and training systems*
  7. *Staff welfare*

# Production capacities throughout the operation

* 1. *Number and type of machines*
  2. *Capacity, Yields*
  3. *Production capacity*
  4. *Capacity of key manufacturing stages and equipment*

# Raw Materials

* 1. *Vendor evaluations including service providers, and validation acceptance and procedures*
  2. *Procedures for selection and purchase of raw materials*
  3. *Quality assurance and storage procedures*

# Preparation of compounded materials

# Moulding

* 1. *Materials used*
  2. *Process and process validation*
  3. *Testing and controls*
  4. *Identification, traceability and status*

# Assembly

* 1. *Equipment*
  2. *Process and equipment validation*
  3. *Process control and monitoring*
  4. *Product bioburden validation*

# Provision for storage and control of work in progress

# Packaging

# Sterilization

# Warehousing

# Distribution procedures

# Quality control plan

# Outgoing product quality

# Quality system and documentation

* 1. *Document control*
  2. *Management review*
  3. *Contract Review*
  4. *Design and Development*
  5. *Identification and traceability*
  6. *Customer Complaint Analysis*
  7. *Corrective and Preventive Actions*
  8. *Change controls*
  9. *Process Validations*
  10. *Post - Market surveillance*
  11. *Environmental Control*
  12. *Control of nonconforming products –scrap security*
  13. *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)