**ASSESSMENT OF MALE LATEX CONDOM**

**PRE-QUALIFICATION APPLICATION**

**Manufacturer’s Name & Address**:

**Date**:

| **Documents** | **Information required in the WHO /UNFPA Guidelines, 2010[[1]](#endnote-1)** | | **Accepted/**  **Not Accepted** | **Comments** |
| --- | --- | --- | --- | --- |
| *1.Expression of interest* | 1.1 Cover Letter |  |  |  |
| 1.2 Documents in English |  |  |  |
| *2.Product Dossier* | 2.0 Table of Contents |  |  |  |
| 2.1 Product characteristics | Widths, thickness range, lengths, shapes, textures, lubricants, flavours, finishing powders, colours, ancillary components, other |  |  |
| 2.2 Regulatory approvals | Local, country, regional, regulatory |  |  |
| 2.3 Raw materials | All listed  Chemical brand, name & function |  |  |
| 2.4 Suppliers | Name |  |  |
| Street address & Country |  |  |
| 2.5 Manufacturing sites (all used for product components) | Name & address |  |  |
| Contact details |  |  |
| Description of site activity |  |  |
| 2.6 Risk management | Plan according to ISO 14971 & ISO 13485 |  |  |
| 2.7 Finished product specifications | Compliance to ISO 4074 |  |  |
| Compliance to WHO |  |  |
| 2.8 Compliance to WHO/UNFPA General Requirements | Confirmation of raw materials |  |  |
| Evidence of biocompatibility testing & summary of reports |  |  |
| No lycopodium or talc |  |  |
| Monitoring of protein levels |  |  |
| Monitoring of bioburden |  |  |
| 2.9 Stability data | Data supporting shelf-life claims in line with ISO 4074 |  |  |
| 2.10 Labelling | Individual packaging |  |  |
| Inner boxes |  |  |
| Exterior shipping cartons |  |  |
| Example of additional information supplied with condoms |  |  |
| *3. Site Master File* | 3.0 | Table of contents |  |  |
| 3.1 General information | Name & address |  |  |
| Contact info for address(es) |  |  |
| Corporate structure |  |  |
| Manufacturing capacity (dipping, electronic, & packaging) |  |  |
| Manufacturing history |  |  |
| Other onsite manufacturing activities |  |  |
| Condom types manufactured onsite |  |  |
| 3.2 Manufacturing certifications | ISO 13485/ISO 9001 |  |  |
| Others |  |  |
| 3.3 Personnel | Total number employed |  |  |
| Breakdown of number of employees by level/category |  |  |
| Organizational chart |  |  |
| Key personnel qualifications |  |  |
| Health policy & procedure summary |  |  |
| Staff training procedures/record maintenance |  |  |
| Health and safety |  |  |
| External assistance |  |  |
| 3.4 Premises & Equipment | Site plan/description |  |  |
| Nature of building construction |  |  |
| Ventilation system description |  |  |
| Compounding area description |  |  |
| Storage area description (quarantined materials, work in progress, and finished goods) |  |  |
| Water systems, Sanitation, waste treatment descriptions |  |  |
| Preventive maintenance |  |  |
| Production equipment description |  |  |
| Calibration and recording systems |  |  |
| Cleaning specs & procedures |  |  |
| Microbiological contamination control procedures |  |  |
| 3.5 Documentation Control | Arrangements for the preparation, revision and distribution of management system documentation |  |  |
| 3.6 Record handling |  |  |  |
| 3.7 Production | Brief description of production operations |  |  |
| Summary of material handling procedures (starting materials, rejected materials, finished product ect) |  |  |
| Validation process information |  |  |
| 3.8 Risk management plan | Summary of risk management assessment undertaken in accordance with ISO 14971 |  |  |
| 3.9 Quality control | Description of QC system |  |  |
| Sampling and testing procedures |  |  |
| Final release process |  |  |
| 3.10 Distribution, complaints & product recall | Procedure for Lot traceability |  |  |
| Customer complaints/product recall procedures |  |  |
| 3.11 Self-inspection | Short description of self-inspection (audit) system |  |  |
| 3.12 Corrective & preventive actions | Brief description of procedures used in control design and development |  |  |
| 3.13 Design and development control procedures | Brief description of procedures used to implementing corrective/preventive action |  |  |

**Comments and recommendation post document review:**

1. The requirements indicated in this form are a summary of the requirements listed in Male Latex Condom: Specification, Prequalification and Guidelines for Procurement, 2010. This document should be referenced for a full description of requirements. [↑](#endnote-ref-1)