**ASSESSMENT OF TCu380A**

**PRE-QUALIFICATION APPLICATION**

Manufacturer’s name & physical address:

Date:

Review team:

Document Review No.:

| **Documents** | **Information required as in the**  ***WHO /UNFPA Technical Specification and Prequalification Guidance, 2016[[1]](#endnote-1)*** | | **Accepted/**  **Not Accepted** | **Comments from UNFPA** | **Reply from Manufacturer** |
| --- | --- | --- | --- | --- | --- |
| ***1.Expression of interest*** | 1.1 Cover Letter |  |  |  |  |
| 1.2 Accompanying documents in English |  |  |  |  |
| ***2.Product Dossier*** | Table of contents |  |  |  |  |
| 2.1 Brand names | List of approved brand names |  |  |  |
| 2.2 Samples | 10 samples in final packaging provided. Package integrity.  For packaging and labelling, see 2.10 |  |  |  |
| 2.3 Regulatory approvals for the product | Local, country and regional |  |  |  |
| 2.4 a) Raw materials | Confirmation of raw materials  (as per table Annex IV 2.4))  Chemical name, manufacturer & function |  |  |  |
| 2.4 b) Suppliers | Name |  |  |  |
| Street address & Country |  |  |  |
| 2.4 c) Manufacturing sites  (including sites for product components) | Name & address |  |  |  |
| Contact details |  |  |  |
| Description of site activity |  |  |  |
| 2.5 Evidence of biocompatibility testing | Verification in line with *WHO/UNFPA techn. specs. 2016.*  Summary reports, incl. toxicologists reports. |  |  |  |
| 2.6 Stability | Shelf-life before insertion data |  |  |  |
| 2.7 Bioburden control and terminal sterilization | Description of procedure |  |  |  |
| Validation procedure |  |  |  |
| Details of contract facilities: Name, address,  ISO 13485 certification |  |  |  |
| Data on residuals |  |  |  |
| 2.8 Finished product specifications | Compliance to ISO 7439 |  |  |  |
| Compliance to WHO/UNFPA technical specification |  |  |  |
| 2.9 In-process control and product release testing | Tests and acceptance criteria performed at critical steps in the manufacturing process.  Deviations |  |  |  |
| 3 Lots final release test reports |  |  |  |
| 2.10 Packaging and labelling specification (from sample, artwork and/or photos) | Primary package insert,  Inner Box,  Exterior Shipping Carton. |  |  |  |
| 2.11 Risk management of the product | Risk Management Plan in line with *ISO 14971 & ISO 13485* |  |  |  |
| 2.12 Design and development | Procedures |  |  |  |
| ***3. Site Master File*** | 3.0 | Table of contents |  |  |  |
| 3.1 General information | Name & physical address of manufacturing site |  |  |  |
| Contact info for address(es) |  |  |  |
| Corporate structure |  |  |  |
| Manufacturing capacity (moulding, assembly, packaging, sterilization) |  |  |  |
| Manufacturing history |  |  |  |
| Other onsite manufacturing activities |  |  |  |
|  | Sales of past three years |  |  |  |
| 3.2 Manufacturing certifications | ISO 13485  ISO 9000 Series  ISO 14001 |  |  |  |
| Others |  |  |  |
| Last *ISO 13485* Audit report |  |  |  |
| 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 |  |  |  |
| Personnel hygiene and safety requirements, protective clothing |  |  |  |
| Health and safety policy |  |  |  |
| External assistance |  |  |  |
| Operating hours and shift for personnel |  |  |  |
| 3.4 Premises & Equipment | Site plan/description |  |  |  |
| Nature of building construction |  |  |  |
| Ventilation system description, incl. prevention of product contamination |  |  |  |
| Cleaning process for manufacturing area and equipment |  |  |  |
| Procedures for staff entering clean areas |  |  |  |
| Procedures for laundering clothin |  |  |  |
| Procedures for monitoring bioburden levels in product. area and on product |  |  |  |
| Bioburden validation reports |  |  |  |
| Maintenance programmes for premises |  |  |  |
| Main equipment used in production and laboratories |  |  |  |
| Preventative maintenance programmes for main equipment in production and laboratories |  |  |  |
| Validation protocols and calibration procedures |  |  |  |
| 3.5 Record handling | Safe storage and retrieval of records |  |  |  |
| 3.6 Production | Production operations |  |  |  |
| Summary of material handling procedures (starting materials, rejected materials, finished product etc.) |  |  |  |
| Arrangements for handling rejected materials and products |  |  |  |
| Validation process information |  |  |  |
| 3.7.1 Quality control | Description of QC system |  |  |  |
| Sampling and testing procedures |  |  |  |
| Final release process |  |  |  |
| 3.7.2 Documentation control | Arrangements for management system documentation |  |  |  |
| 3.7.3 Risk management plan | Summary of risk management assessment in accordance with *ISO 14971* |  |  |  |
| 3.7.4 Self-inspection | Short description of self-inspection (audit) system |  |  |  |
| 3.7.5 Corrective & preventive action | Procedures for identifying, implementing and completing CAPA |  |  |  |
| 3.10 Distribution, complaints & product recall | Arrangements and recording systems for distribution |  |  |  |
|  | Customer complaints/product recall procedures |  |  |  |

**Comments and recommendation post document review:**

1. The requirements indicated in this form are a summary of the requirements listed in The *TCu380A Intrauterine Contraceptive Device (IUD) Technical Specification and Prequalification Guidance 2016* - See more at: <http://www.unfpa.org/resources/copper-bearing-intrauterine-devices#sthash.iNvYZk2e.dpuf>. This document should be referenced for a full description of requirements. [↑](#endnote-ref-1)