**Finished Good Specifications for CuT380 A**

| **Parameters** | **Specifications** |
| --- | --- |
| Component | T- Frame | * Material: LDPE (Du Pont™ 20) + BaSO4 (USP grade, 15 -25 %)
* Length (Horizontal Arm) : 31.5 – 33.0 mm
* Length (Vertical Arm/Stem) : 35.5 – 37.0 mm
* Diameter (Horizontal Arm): 1.5 - 1.7 mm
* Diameter (Vertical Arm/Stem): 1.4 - 1.6 mm
* T piece ball diameter : 2.3 – 3.7 mm
 |
| Copper wire  | * Material: Copper OFE 99.99% (Other elements not more than 50 ppm)
* Diameter : 0.250 mm - 0.260 mm
 |
| Copper Sleeve/Collar | * Material: Copper OFE 99.99% (Other elements not more than 50 ppm)
* Weight of Copper Collar: 65.7 – 71.7 mg
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| * Position of Collar: 5.4 ± 0.4 mm from T frame Horizontal Arm
 |
| * Copper Collar Outer Diameter (Swaged) : 2.05 - 2.11 mm
 |
| Suture thread | * Material: HDPE, Phillips Marlex 6006/ 6007 + 0.4 up to 1%TiO2 (Rutile) USP grade
* Length: 10.5 - 12.5 cm (105 mm – 125 mm)
 |
| Insertion Tube | * Material: HDPE, Phillips Marlex 6006/ 6007
* Length : 204 - 208mm
* Outer Diameter: 4.3 mm - 4.6 mm
* Inner diameter: 3.6 mm - 3.9 mm
 |
| Flange | * Material: Medical grade Polyvinyl Chloride resin + FDC Dye\* (optional)
 |
| Solid Rod | * Material: Polypropylene + 0.5 % TiO2 (Rutile) USP grade
* Fit in insertion tube : Slide smoothly in insertion tube
* Length: 185 - 195 mm
* Tip Diameter: 2.4 - 2.8 mm
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| **Parameters** | **Specifications** |
| --- | --- |
| Tests | Visual Inspection | Clean without any contamination like black spots, particulate matter, seal is uniform & continuous, free from tears, creases & pin holes. When peeled, the sealed show continuous white layer. |
| Winding | Uniform winding without Protrudence |
| Weight/Mass of copper wire | 165 - 187 mg/frame |
| Pouch Integrity Test  | Tyvek-Film Pouch: No Leakage at 200 mm-Hg Pressure for 2 minutes |
| Film-Film Pouch : No Leakage at 600 mm-Hg Pressure for 2 minutes |
| Pouch Peel Strength | 4.4 N/2.54cm to 19.0 N/2.54 cm |
| Tie/Device Breaking strength | NLT 9.5 N |
| Copper collar Displacement/ Retention force | NLT 6.86 N |
| Memory test | NMT 5.0 mm |
| Flange Displacement Force | 2.0 N – 9.0 N |
| Dosimetry Test | 25 kGy – 35 kGy |
| Sterility Test | Should Comply Sterility Assurance Level 10-6 |
| Method of Sterilization | - | CuT380 A shall be sterilized by Gamma radiation |
| Shelf life | - | 5 years |
| Packing | Primary packing | * Tied Cu T pieces with insertion components that is Insertion Tube, solid rod, Flange & Label Insert are packed in one pouch containing one side uncoated 1073B Tyvek paper & other side polyethylene film (Tyvek-Film Pouch).
* Tied Cu T pieces with insertion components that is Insertion Tube, solid rod, Flange & Label Insert are packed in one pouch containing both side polyethylene film.(Film-Film Pouch).
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| Secondary packing | * One Sterile Primary packed IUD is packed in one Monocarton with one IFU & one Patient card. Such 10 Monocartons are packed in one Inner Box. Such 20 inner Boxes are packed in shipper carton
* 50 Sterile Primary Packed IUDs are packed in One inner Box of 50 pcs with 10 IFUs. Such inner Boxes are packed in Shipper carton
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**Note:**

* Primary & Secondary packing May vary as per customer requirement
* The Product shall be released on Sterility Test &/or Dosimetry test as per customer requirement