**Checklist of required documentation**

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| **Product class  (EC MEDDEV)** | **Minimum documentation required** Documents to be submitted must be true and valid copies. All documents submitted must be in English or be accompanied with certified translation. |
| **class I** (non-measuring, non-sterile and/or non-reusable surgical instrument, rsi) | ☐ Copy of ISO 13485\* (or ISO 9001\*) QMS certificate. ☐ A signed and dated Declaration of Conformity (DoC) according to ISO 17050 stating compliance to the relevant ISO standards and directives (for manufacturer), and which has reference to the offered product.  ☐ Photo of the product and packaging (at various angles if necessary, preferably in a format where the dimensions and features can be visually verified from the photos). |
| **class I measuring class I sterile class I rsi class IIa** | ☐ Copy of EC certificate (referencing the name/number of the notifying body), and/or 510k FDA clearance, and/or approval letter or certificate from a National Regulatory Body. ☐ A signed and dated DoC according to ISO 17050 stating compliance to critical ISO standards (e.g. for sterilization, ISO 13485 QMS) and directives, and which has reference to the offered product. **Note***:* If a sterilization activity is subcontracted to a third party, ISO 13485 QMS compliance is also required from the subcontracting company. ☐ Photo of the product and packaging (at various angles if necessary, preferably in a format where the dimensions and features can be visually verified from the photos). |
| **class IIb  class III** | ☐ Copy of EC certificate (referencing the name/number of the notifying body) with an additional copy EC Design Examination certificate, and/or 510k/PMA FDA clearance, and/or approval letter or certificate from a National Regulatory Body. ☐ A signed and dated DoC according to ISO 17050 stating compliance to critical ISO standards (e.g. ISO 13485 QMS) and directives, and which has reference to the offered product. Proof of compliance to ISO standards in a form of copies of certificates shall be submitted if available. ☐ Photo of the product and packaging (at various angles if necessary, preferably in a format where the dimensions and features can be visually verified from the photos). |

\*) UNFPA accepts the versions of currently active standards, which are recognized by the International Organization for Standardization at the time of document submission.

**Examples of products in each of the Medical Device EC MEDDEV**

Class: Class I (non-measuring, non-sterile and/or non-reusable surgical instrument) Aprons, bags, baskets, bowls, etc. (largest item class group in UNFPA procurement catalog).

Class I (measuring, sterile and/or reusable surgical instrument) Thermometers, scales, catheters, cytobrushes, sterile surgical and gynecological instruments, sterile gloves and supplies, reusable surgical and gynecological instruments, etc.

Class IIa Cannulas, needles, blades, pumps (manual, electrical), resuscitators, etc. (Many of the class IIa products are also sterile products.)

Class IIb and III

Anaesthesia machines, cryosurgical units, sutures, baby warmers and incubators, infusion pumps etc.