Fast Track Procurement Questionnaire
for Medical Devices

PART I. Manufacturer information

Bidder (if not manufacturer): Click here to enter text.

Manufacturer:
Name of manufacturer: Click here to enter text.
Country: Click here to enter text.
Address (office): Click here to enter text.
Address (manufacturing site(s)): Click here to enter text.
Contact person's name: Click here to enter text.
Email: Click here to enter text.
Phone: Click here to enter text.

PART II. Product information

Product Identification (Trade name, Type, Model, Package size, Intended use, etc.)**:**
Click here to enter text.

Product Code, Reference number(s): Click here to enter text.

Product details (materials, dimensions, size, volume, features, etc. For electrical devices specify voltage, frequency and plug supplied.)**:** *(E.g. If a stainless steel product, identify AISI type or composition. If a plastic product, identify type or composition.)*
Click here to enter text.

PART III. Regulatory Status

3.1 Is the product CE marked? Certification body and number: Click here to enter text.	☐	Yes	Start Date: Click here to enter text. Expiry Date: Click here to enter text.
	☐	No	
3.2 Is the product FDA approved? 510k clearance #: Click here to enter text. PMA clearance #: Click here to enter text.	☐	Yes	Start Date: Click here to enter text. Expiry Date: Click here to enter text.
	☐	No	
3.3 Is the product approved by National Regulatory Agency or Department? Name of agency and type of approval: Click here to enter text.	☐	Yes	Start Date: Click here to enter text. Expiry Date: Click here to enter text.
	☐	No	
3.4 Provide details of <u>any other</u> current regulatory approvals for this product. Name of jurisdiction and type of approval: Click here to enter text.	☐	Yes	Start Date: Click here to enter text. Expiry Date: Click here to enter text.
	☐	No	

3.5 Manufacturer QMS ISO 13485 Yes ☐ No ☐
QMS ISO 9001 Yes ☐ No ☐

a. Certification body and number: Click here to enter text.
b. Expiration date: Click here to enter text.

3.6 FOR STERILE PRODUCTS - If the manufacturing process is subcontracted:

Name and address of the subcontractor	QMS certification of the subcontractor - Identify Regulatory body and/or number and expiry date
Click here to enter text.	Click here to enter text.

3.7 FOR ELECTRICAL or BATTERY-OPERATED PRODUCTS

If the device contains Lithium metal and Lithium ion batteries, does it comply with clause 38.3 of the recommendations on "Transport Of Dangerous Goods" from the United Nations?	Yes ☐ No ☐
Does it comply with the latest IATA Dangerous Goods Regulations (DGR)?	Yes ☐ No ☐
Testing laboratory, Test Report reference, specify standard	Click here to enter text.

PART IV. Checklist of required documentation

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.