**Q.1 Can you please confirm that partial bids are allowed? Is a partial bid for one schedule allowed as well? E.g. would a bid for 5 out of 10 products in Schedule 1 be accepted? Or is it obligatory to submit bids for complete schedules, whereas not every schedule must be covered?**

A.1 Indeed, partial bids are allowed. It can be bids for individual schedules, or even partial bid for one schedule as per your example. We formally cover this issue in the RFP document on page 21, section 1.2:

*1.2 Partial Proposals. UNICEF will accept partial Proposals (i.e. proposal for one schedule, technically and commercially compliant, or in some cases proposals for individual items).*

**Q.2  Could you also please confirm whether section 7. on page 20 of the RFP means that alternative offers won’t be accepted? I.e. within our one bid we should not include more than one offer for a single line/item?**

A.2 Alternative offers will be accepted. Preferably not more than one main offer and one alternative offer (for a given product), so two offers for the same product (i.e. in a situation where you have two models for the same product that both fit with our requirements).

**Q.3 In relation to product 120 (portable autorefractor).**

**Q3.1 Section Title Line 3**

**We are unsure how "portability" will be gauged in the pass / fail response to G-42?**

* **There seems to be no definition for what is considered a "portable" autorefractor.**
* **For instance, most desktop autorefractors weigh 15 to 25kg, which is technically portable but not practically portable.**

A.3 Portable autorefractor, means, an autorefractor is designed to be operated handheld powered by batteries. But also, it should have a desktop set-up which it can be fitted with and operated on, also.

**Q.3.2 Section C-14**

**Would it be more appropriate to ask for the relevant regulatory approval documentation, which is specifically important given the recent updates to classifications made by the EU Medical Device Regulations?**

* **The pass / fail question asks whether the autorefractor is a "class 1" device.**
* **However, there are autorefractors that are widely used across the world that are "class 2" devices.**
* **For instance, our portable handheld autorefractor is a CE Mark approved Class 2 device that is used in 45 countries by governments, NGOs, and the commercial sector.**
* **In the USA - it is classified as a Class 1 exempt - though all the QMS, certificates are issued to the manufacturing site in Spain (and classed as Class 2)**

A.3.2 It can be UE class I/FDA class 1 or higher. All documentation that supports the declaration of conformity should be presented. This includes all documentation related to the clinical performance of the medical device.

**Q.3.3 Section G-32**

**We are unsure of the intent of the question (and therefore do not understand what answer would be appropriate for us to submit)?**

* **The pass / fail question asks for a "desktop set up."**
* **However, state-of-the-art portable autorefractors are handheld.**

A.3.3 Portable autorefractor, means, an autorefractor is designed to be operated handheld powered by batteries. But also, it should have a desktop set-up which it can be fitted with and operated on, also.

**Q.3.4 Section G-43**

**It is unclear to us what type of device is being sought for the program - a desktop or handheld autorefractor?**

* **The question is related to battery operation but another section seems to be asking for a desktop device (which are not battery powered).**

A.3.4 Portable autorefractor, means, an autorefractor is designed to be operated handheld powered by batteries. But also, it should have a desktop set-up which it can be fitted with and operated on, also.

**Q.3.5 Section I-55, K-71, K-72**

**How should we respond to these pass / fail questions which are not applicable to our handheld autorefractor?**

A.3.5 All questions are to be answered. If not applicable, the answer is no. I-55 should have an answer.

**Q.4 We are concerned that there are no specifications for accuracy and reproducibility of measurements by the autorefractor, since clinical accuracy and reproducibility are important specifications to have global health impact.**

A.4 The technical characteristics and performance of the medical device will be considered. All documentation that supports the declaration of conformity should be presented. This includes all documentation related to the clinical performance of the medical device.

**Q.5 Please let us know where we can find the placeholders for:**

* "**Brochures"**
* **"Certificates"**
* **"Technical documents"**

**Are you assuming that we create the "placeholder" for each folder?**

A.5 Brochures, certificates and technical documents should be attached in the technical proposal/submission email. There are no specific placeholders for these. These documents should be optimally "labelled" (saved) in a way that is easy to link to the corresponding product. Supplier can use RFP item reference i.e. "Item 120 Brochure" or "Item 120 Certificate".

It is also important that suppliers keep Commercial Proposal and Technical Proposal separated. We recommend that suppliers clearly identify the emails as below:

**RFP-DAN-2024-503695 - [Company Name] - Technical Proposal – Submission [#] of [#]**

**RFP-DAN-2024-503695 - [Company Name] - Commercial Proposal - Submission [#] of [#]**