

KENYA MEDICAL SUPPLIES AUTHORITY

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All Correspondence should be addressed to Chief Executive Officer

When replying please quote our ref:

REF: KEMSA/PROC/ONT 11/16-17

12th April 2017

To all Bidders,

CLARIFICATION NO. 1

Dear Sir/Madam,

RE: TENDER NO. KEMSA/ONT 11/2016-2017 FOR SUPPLY, INSTALLATION AND COMMISSIONING OF LABORATORY EQUIPMENT

The following are queries raised by interested bidders and responses made as below:

Question 1: Clause ITT 6.3(c) - PG 29 - This clause indicates samples are to be provided. Kindly confirm this is an error as you can appreciate it is not possible to provide samples for Laboratory equipment.

Response: Tender sample are not required. Bidders are required to provide brochures for evaluation.

Question 2: Section 3: Quality Certification- This section states: Three international quality standards bodies have been used for this tender;

- i) ISO 13485 - Medical Device quality management system
- ii) IEC 60601- Requirement for safety of medical electrical equipment
- iii) Council Directive 93/42/EEC- Medical devices

The tenderer shall be required to submit ISO 13485 quality certificate and any one of the two above for the purpose of this tender.

Please note some of the items in the tender do not fall in the category of medical devices. They are classified as General or Analytical Laboratory equipment.

Kindly confirm we can submit the following quality certificates for these items not classified as medical devices: ISO 9001:2008

Response: Tenderers are required to submit certificate of quality issued by an independent recognized authority e.g. ISO, KEBS or equivalent for the equipment. The certificate of quality must be valid and product specific.

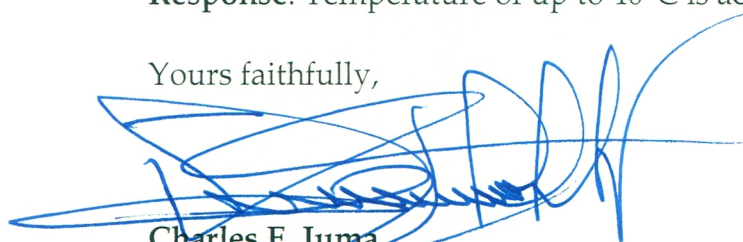
Question 3: You have indicated you require an original Brochure-Please confirm that Print out of the official Manufacturer original brochure will meet this point.

Response: Print outs of the official Manufacturer original brochures are acceptable.

Question 4: Item 5: Disintegration Tester - you have indicated you require a temperature range of 30-50°C degrees. Kindly note Disintegration tests are done at 37°C (internal temperature of body) - There is no need to use temperature above this. Please confirm we can quote for system with temperature up to 40°C, as this is more than sufficient for tests.

Response: Temperature of up to 40°C is acceptable.

Yours faithfully,



Charles E. Juma
Director Procurement
For: Ag. Chief Executive Officer