

Annex 4 – Product Specifications and Technical Requirements

ANNEX 4

PRODUCT SPECIFICATIONS AND TECHNICAL REQUIREMENTS

This Document is to provide the offerors with the product(s) specifications and Technical Requirements for The Procurement of the commodities listed in the RFQ: GHSC-PSM-TO1-CC2-2018-DRC-RO10055262-10056122.

I. Product Specifications

RO10055262

Lot #	Product Category	Product Description	Items UOM	Quantity of Package	Supplier Good Availability Date	Shipping Address
1	Medical Supplies	Bag, Biohazard, Printed, Red, 37 x 48 in, Autoclave, 2 mil, 100 Each	Pack	14		USAID-DRC, CAMELU Magasin 16 usines de la Gecamines, Avenue Lubumbashi Q/ Makomeno Lubumbashi, Congo, CD
2	Medical Supplies	Microcentrifuge Tube 1.5 mL, Conical Bottom, Screw Cap, Sterile, 1000 Pieces	Pack	64		CAMELU
3	Medical Supplies	Ethanol Absolute, Analytical Grade, 1 L	Unit	17		CAMELU
4	Medical Supplies	Dried Blood Spot Collection Kit 903 or TFN, Bundle, 100 Tests	Pack	82		CAMELU
5	Medical Supplies	Dried Blood Spot Collection Kit 903 or TFN, Perforated, Bundle, 100 Tests	Pack	24		CAMELU
6	Medical Supplies	Examination Gloves (Nitrile) Large, Powder-Free, Non-Sterile, ASTM Standard, 100 Each	Pack	13		CAMELU
7	Medical Supplies	Examination Gloves (Vinyl) Medium, Powder-Free, Non-Sterile, 100 Each	Box	13		CAMELU
8	Medical	Examination Gloves	Box	173		CAMELU

Annex 4 – Product Specifications and Technical Requirements

	Supplies	(Latex) Large, Powder-Free, Non-Sterile, 100 Each				
9	Medical Supplies	Examination Gloves (Latex) Medium, Powder-Free, Non-Sterile, 100 Each	Box	517		CAMELU
10	Medical Supplies	Examination Gloves (Latex) Small, Powder Free, Non-Sterile, 100 Each	Box	172		CAMELU
11	Medical Supplies	Disposable Lab Coat, White, Large, 30 Each	Pack	1		CAMELU
12	Medical Supplies	Needle, Multi-Sample, Blood Collection, 21G, 1.5 in, 100 Each	Unit	923		CAMELU
13	Medical Supplies	Blood Collection Tube Holder, Adult, Non-Sterile, 13 - 16 mm, 100 Each	Pack	90		CAMELU
14	Medical Supplies	Pipette Tips, Aerosol Barrier, Sterile, 100-1000 uL, 8 Racks of 96 Tips	Pack	584		CAMELU
15	Medical Supplies	Pipette Tips, 20-200 uL, Aerosol Barrier, Sterile, Graduated, Hinged-Rack, 10 Racks of 96 Tips	Pack	350		CAMELU
16	Medical Supplies	Pipette, Single Channel, Manual, 100-1000 uL, LTS Tips, 2.0 uL Increment, 1 Each	Unit	16		CAMELU
17	Medical Supplies	Pipette, Single Channel, Manual, 10-100 uL, 0.2 uL Increment, 1 Each	Unit	16		CAMELU
18	Medical Supplies	Sharps Container, Cardboard, 5 L, Brown, Disposable, Water Resistant, 1 Each	Unit	195		
19	Medical Supplies	Shoe Cover, Latex-Free, Blue, Disposable, Universal Size, 300 Each	Pack	119		CAMELU
20	Medical	Centrifuge Tube 50	Unit	284		CAMELU

Annex 4 – Product Specifications and Technical Requirements

	Supplies	mL, Polypropylene, Conical Bottom, Flat Screw Cap, Sterile, 500 Each				
21	Medical Supplies	Blood Collection Tube, 4 mL, Plastic, Red Top, 100 Each	Unit	60		CAMELU
22	Medical Supplies	Blood Collection Tube, K2-EDTA, 6 mL, Plastic, Lavender Top, 100 Each	Pack	50		CAMELU
23	Medical Supplies	Blood Collection Tube, K3-EDTA, 10 mL, Plastic, Lavender Top, 1000 Tubes	Case	56		CAMELU
24	Medical Supplies	Disposable Lab Coat, Blue, Medium, 30 Each	Pack	2		CAMELU
25	Medical Supplies	Pasteur Transfer Pipet, Plastic, Graduated, Sterile, 3 mL, 500 Pieces	Pack	432		CAMELU
26	Medical Supplies	Needle, Multi-Sample, Blood Collection, 23G, 0.75 in, Luer, Thin Wall, Green, 100 Each	Box	102		CAMELU
27	Medical Supplies	Bag, Biohazard, Printed, Red, 37 x 48 in, Autoclave, 2 mil, 100 Each	Pack	10		CAMESKIN - Central de Achat des Medicaments Essentiels de, Kinshasa, Av de la Pharmacie No. 39 Baru mbu Kinsh asa, C ongo, CD paulin mang ungu @yah oo.fr
28	Medical Supplies	Microcentrifuge Tube 1.5 mL, Conical Bottom, Screw Cap,	Pack	44		CAMESKIN

Annex 4 – Product Specifications and Technical Requirements

		Sterile, 1000 Pieces				
29	Medical Supplies	Ethanol Absolute, Analytical Grade, 1 L	Unit	10		CAMESKIN
30	Medical Supplies	Dried Blood Spot Collection Kit 903 or TFN, Bundle, 100 Tests	Pack	54		CAMESKIN
31	Medical Supplies	Dried Blood Spot Collection Kit 903 or TFN, Perforated, Bundle, 100 Tests	Pack	16		CAMESKIN
32	Medical Supplies	Examination Gloves (Nitrile) Large, Powder-Free, Non-Sterile, ASTM Standard, 100 Each	Pack	10		CAMESKIN
33	Medical Supplies	Examination Gloves (Vinyl) Medium, Powder-Free, Non-Sterile, 100 Each	Pack	10		CAMESKIN
34	Medical Supplies	Examination Gloves (Latex) Large, Powder-Free, Non-Sterile, 100 Each	Unit	115		CAMESKIN
35	Medical Supplies	Examination Gloves (Latex) Medium, Powder-Free, Non-Sterile, 100 Each	Unit	344		CAMESKIN
36	Medical Supplies	Examination Gloves (Latex) Small, Powder Free, Non-Sterile, 100 Each	Box	115		CAMESKIN
37	Medical Supplies	Disposable Lab Coat, White, Large, 30 Each	Pack	1		CAMESKIN
38	Medical Supplies	Needle, Multi-Sample, Blood Collection, 21G, 1.5 in, 100 Each	Pack	616		CAMESKIN
39	Medical Supplies	Blood Collection Tube Holder, Adult, Non-Sterile, 13 - 16 mm, 100 Each	Pack	60		CAMESKIN
40	Medical Supplies	Pipette Tips, Aerosol Barrier, Sterile, 100-1000 uL, 8 Racks of 96 Tips	Pack	390		CAMESKIN
41	Medical Supplies	Pipette Tips, 20-200 uL, Aerosol Barrier, Sterile, Graduated,	Pack	234		CAMESKIN

Annex 4 – Product Specifications and Technical Requirements

		Hinged-Rack, 10 Racks of 96 Tips				
42	Medical Supplies	Pipette, Single Channel, Manual, 100-1000 uL, LTS Tips, 2.0 uL Increment, 1 Each	Unit	10		CAMESKIN
43	Medical Supplies	Pipette, Single Channel, Manual, 10-100 uL, 0.2 uL Increment, 1 Each	Unit	10		CAMESKIN
44	Medical Supplies	Sharps Container, Cardboard, 5 L, Brown, Disposable, Water Resistant, 1 Each	Unit	130		CAMESKIN
45	Medical Supplies	Shoe Cover, Latex-Free, Blue, Disposable, Universal Size, 300 Each	Pack	80		CAMESKIN
46	Medical Supplies	Centrifuge Tube 50 mL, Polypropylene, Conical Bottom, Flat Screw Cap, Sterile, 500 Each	Pack	190		CAMESKIN
47	Medical Supplies	Blood Collection Tube, 4 mL, Plastic, Red Top, 100 Each	Pack	40		CAMESKIN
48	Medical Supplies	Blood Collection Tube, K2-EDTA, 6 mL, Plastic, Lavender Top, 100 Each	Pack	30		CAMESKIN
49	Medical Supplies	Blood Collection Tube, K3-EDTA, 10 mL, Plastic, Lavender Top, 1000 Tubes	Case	37		CAMESKIN
50	Medical Supplies	Disposable Lab Coat, Blue, Medium, 30 Each	Pack	2		CAMESKIN
51	Medical Supplies	Pasteur Transfer Pipet, Plastic, Graduated, Sterile, 3 mL, 500 Pieces	Pack	288		CAMESKIN
52	Medical Supplies	Needle, Multi-Sample, Blood Collection, 23G, 0.75 in, Luer, Thin Wall, Green, 100 Each	Box	69		CAMESKIN

Annex 4 – Product Specifications and Technical Requirements

RO10056122

Lot #	Product Category	Product Description	Items UOM	Quantity of Package	Supplier Good Availability Date	Shipping Address
1	Medical Supplies	Blood Collection Tube, K2-EDTA, 6 mL, Plastic, Lavender Top, 100 Eac	Pack	50		USAID- DRC, CAMELU Magasin 16 usines de la Gecamines, Avenue Lubumbashi, Congo
2	Medical Supplies	Blood Collection Tube, K3-EDTA, 10 mL, Plastic, Lavender Top, 1000 Tubes	Case	56		CAMELU
3	Medical Supplies	Blood Collection Tube, K2-EDTA, 6 mL, Plastic, Lavender Top, 100 Each	Pack	30		Cameskin- Central de Achat des Medicaments Essentiels de, Kinshasa, Av de la Pharmacie No. 39- Barumbu Kinshasa, Congo
4	Medical Supplies	Blood Collection Tube, K3-EDTA, 10 mL, Plastic, Lavender Top, 1000 Tubes	Case	37		CAMESKIN

2. Conformity with Quality and Products Standards

Offerors and the products presented and delivered must fully comply with the following eligibility requirements:

1. Manufacturer(s) shall conform to the quality standards set by the International Organization for Standardization and/or the US FDA Quality System Regulations. Manufacturer must be quality assured with certifications like ISO 9001:2000 or ISO 13485 or approved by standards regulatory bodies in country of manufacturer, which bodies must be accredited by or affiliated to standards institutes like ISO, with copy of certifications(s) included. A copy of the manufacturer(s) certifications(s) must be provided. If a documented Quality Management System is not available past performance or other alternative means may be considered.

2. Product Quality Standards by Product Category:

[Note to offeror: When a product category is not specified below no additional product quality standards are required.]

- **Diagnostic: Medical Supplies:** Product shall have evidence of US FDA Clearance (PMA/510K) or CE Mark (SRA)* Certificate, A certificate of analysis shall be provided for each lot procured; For sterile products, a certificate of sterility shall be provided for each lot. The label shall include manufacturer/distributor information, lot number, manufacturing date, expiration date and storage conditions.

Annex 4 – Product Specifications and Technical Requirements

- **Medical Supplies:** Product shall have evidence of US FDA Clearance (PMA/510K) or CE Mark (SRA)* Certificate. Medical supplies shall be labeled with manufacturer/distributor information, lot number, manufacturing date and expiration date. A certificate of analysis/conformance shall be provided for each lot procured. For sterile products, a certificate of sterility shall be provided for each lot.
- **Laboratory Reagent:** Product shall be labeled with manufacturer/distributor information, lot number, manufacturing date and expiration date. A certificate of analysis shall be provided for each lot procured.

3. Quality Assurance Provision

According to GHSC-PSM Standard General Contract Terms and Conditions.

4. Pre-Acceptance Sampling and Testing requirements

When applicable, offeror shall coordinate with GHSC's quality assurance contractor, Global Health Supply Chain Program - Quality Assurance (GHSC-QA) implemented by FHI360, who will implement inspection, sampling, quality assurance testing and acceptance within the terms and conditions outlined below.

5. Sampling requirements

GHSC-QA reserves the right to sample from the Manufacturer's facility and to perform or cause to be performed any of the tests and inspections set forth in this purchase description to assure that supplies and services conform to the prescribed requirements.

[Instruction (to be deleted): Sampling may be required for Diagnostic: Rapid Test Kit (Non-HIV), Diagnostic Pregnancy Tests, etc.]

6. Test method

When required, product will be tested in accordance with established GHSC-QA protocols. The manufacturer will be requested to provide the specifications and test methods utilized for product release. In instances when a method transfer is required, manufacturer will be requested to provide for method transfer and routine test reference substances required for performing the laboratory QC tests.

Annex 4 – Product Specifications and Technical Requirements

7. Lead Time

Please provide the estimated lead time

8. Lot disposition

Where testing is not required, it is not applicable. Product is released per manufacturer specification where applicable.

9. Manufacturer Furnished inspection data

When applicable, Manufacturer shall provide a summary of the final inspection results for each lot available for delivery under this contract prior to shipment to GHSC-PSM. Individual test reports shall be maintained by the Manufacturers, and shall be made available for inspection by GHSC-QA.

10. Post-Acceptance inspection

Each product delivered to GHSC-PSM shall comply with all product specifications and test procedures (when applicable) specified through the product shelf-life or life cycle.

GHSC-QA reserves the right to sample from and perform or cause to be performed any of the tests and inspections set forth in this purchase description to assure that supplies and services continue to conform to the prescribed requirements after product acceptance. In the event, products are determined to not be fully compliant, the Offeror shall be required to remedy any defects or faults

11. Product documentation

The following product documentation is requested as part of this solicitation:

- a. Evidentiary documentation of Manufacturer QMS certification by internationally recognized standardization body
- b. Product information data sheet
- c. Manufacturer's product reference number and description
- d. Manufacturer's contact details, including link to website
- e. Recommended storage and transportation conditions
- f. Commercial brochure
- g. When applicable, country product registration or import permit to the country of destination.
- h. Certificate of conformance CE Mark (SRA), US FDA clearance (PMA/510K) or WHO Prequalification, or other when specified above in "Product Quality Standards by Product Category"

The following product documentation is requested as part of the procurement process:

- A certificate of analysis/conformance for each lot shall be provided as specified in product quality standards section

Annex 4 – Product Specifications and Technical Requirements

- Additional product documentation may be requested.

12. Shelf Life

Goods with a Shelf Life must be freshly manufactured within the past 12 months, and thus have maximum possible shelf life. Goods with a maximum possible shelf life of less than 24 months shall have at least 85% of shelf life remaining when delivered. Goods with a maximum possible shelf life of more than 24 months shall have at least 24 months, or 85%, of shelf life remaining whichever is longer, when delivered.

No Goods will be accepted which do not comply with these requirements unless Chemonics has agreed in writing to different requirements, in which case the Goods must strictly comply with those modified requirements. The period of warranty referenced in Section VI for all goods with a shelf life shall be no less than the minimum Shelf Life of the Goods.

13. Shipping Specifications

Please provide estimated weight, volume, dimensions and number of pieces. The Supplier will be required to provide a Packing List with items, weights and dimensions per pallet as well as a Detailed Packing List listing aggregate quantities per item, weights and dimensions as well as shipping conditions applicable to the items (temperature control, i.e. frozen, 2-8C, 5-25C, ambient) and all batch numbers for each, i.e. carton 1 of 50, batch #2, qty 500. Supplier is required to comply with packaging and shipping instructions related to the INCOTERM.

Temperature control: Supplier shall provide a separate set of commercial documents for each of the temperature control category groups, i.e. frozen minus 20 Celsius, cold chain 2-8 Celsius, 15-25 Celsius, ambient 2-30 Celsius. Supplier shall guarantee frozen minus 20 Celsius and cold chain shipments 2-8 Celsius for a duration of 96 hours and shall provide temperature loggers for each and every order that is frozen minus 20 Celsius and cold chain shipments 2-8 Celsius.

14. Packaging and Packing

The products to be supplied under this contract will be packed and protected to prevent damage or deterioration during transportation and storage. The box will be manufactured of a standard heavy-duty material appropriate for the destination countries where high heat and humidity is prevalent, that will withstand export handling and rough treatment, and help ensure the quality of the product.

15. USAID Marking Requirements

Chemonics reserves the right to require USAID marking as below: The Manufacturer(s) will be responsible for ensuring that all export shipping cartons, whether shipped from the United States or from any other source country, carry the official USAID emblem.

Annex 4 – Product Specifications and Technical Requirements

Emblems will be affixed by metal plate, decal, stencil, label, tag, or other means, depending upon the type of commodity or export shipping carton and the nature of the surface to be marked. The emblem on each export-shipping carton will be affixed in a manner which assures that the emblem will remain legible until the carton reaches the consignee. The size of an emblem will vary depending upon the size of the commodity and the size of the package or export-shipping carton. The emblem will, in every case, be large enough to be clearly visible at a reasonable distance.

Emblems will conform in design and color to samples available from USAID and can be found at: <http://www.usaid.gov/branding/>.

Emblems will be obtained by the Manufacturer(s) at its expense in the quantity and type required. The Manufacturer(s) will be required to affix USAID emblems in accordance with the marking requirements stated above.

A list of the emblem suppliers can be found at: <http://www.usaid.gov/branding/suppliers>.

16. Innovation

16.1. Bar coding

Not applicable for this procurement.

16.2. EDI (Electronic Data Interchange)

Not applicable for this procurement.

16.3. Vendor Management Inventory

Not applicable for this procurement.

16.4. Global Trade Item Number (GTIN)

Not applicable for this procurement