# KENYA MEDICAL SUPPLIES AUTHORITY

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KENYA MEDICAL SUPPLIES AUTHORITY — YOUR PARTNER IN HEALTHCARE

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*All Correspondence should be addressed to Chief Executive Officer*

**When replying please quote our ref:**

KEMSA/GOK-AFD-2021-2022 -OIT 001 Date: 9th September, 2021

## ADDENDUM 1:

**Attn.: All Prospective Bidders**

**RE: KEMSA/GOK-AFD-2021-2022 -OIT 001 FOR SUPPLY OF PERSONAL PROTECTIVE EQUIPMENT (PPE's)**

In accordance with ITT Clause 7.1 (Clarification of Tendering Document) of the Open International Tender (OIT) issued under the above reference, we hereby respond to a query raised by a prospective bidder:

**Question**

Item No. 4- Gloves Examination Latex, it is indicated as reserved for Local Manufactures on the NOTE at the bottom of the Price Schedule. Please clarify.

**Response**

We wish to clarify as follows:

(i) Item No. 4- Gloves Examination Latex, is **NOT** reserved for Local Manufacturers but open to all interested bidders.

(ii) **Item 5 - Face Shield and Item 7 - Mask, Medical (Surgical disposable masks) - 3 ply are the items reserved for Local manufacturers.** Agents /Distributors are **not** eligible.

Find attached revised technical specifications and price schedule for ease of reference.

Yours faithfully,

**EDWARD BULUMA**
**FOR: Ag. CHIEF EXECUTIVE OFFICER**

PRICE SCHEDULE FOR GOODS

| | 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| No | Product Description | UOM | Quantity Unit Packs Offered | (a) Unit Price FOB port of Loading | (b) Inland transport, insurance and other local costs incidental to delivery | (c) Other incidental cost as defined in the SCC | Total Unit Pack price (4a+b+c) | Total Price (3 x5) | Manufacturer | Delivery Period | Delivery Period Offered by Bidder |
| 1. | PPE consistency of Overall with Hood and Boot Covers (Large ) | Kit | 6,000 | | | | | | | 1 to 12 weeks | |
| 2. | PPE consistency of Overall with Hood and Boot Covers (Medium ) | Kit | 14,000 | | | | | | | 1 to 12 weeks | |
| 3. | Apron Disposable | Pack of 100's | 12,000 | | | | | | | 1 to 12 weeks | |
| 4. | Gloves Examination Latex | Pack of 50 | 1,000 | | | | | | | 1 to 12 weeks | |
| 5. | Face Shield | Piece | 10,000 | | | | | | | 1 to 12 weeks | |
| 6. | Mask Particulate Respirator (N95). | Piece | 25,000 | | | | | | | 1 to 12 weeks | |
| 7. | Mask , Medical (Surgical disposable masks – 3 ply | Pack of 50 | 1,800 | | | | | | | 1 to 12 weeks | |

***Note:** *In case of descripancy between the unit price and total, the unit price shall prevail*

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| DDP, Named Final destination KEMSA Warehouse – Nairobi – Kenya | Currency | Grand Total Price (Sum of Column 6) | In Figures | |
| | | | In words | |

Procurement financed under GOK-AFD shall be subjected to any customs duties, tariffs, import taxes, or similar levies (including Value Added Tax) imposed under Laws in effect in Kenya..

| Bidder's Name and Address | Date | Signature and Stamp |
|---|---|---|
| | | |

**NOTE:**

- **Item 5&7: Reserved for Local manufacturers. Agents /Distributors are not eligible to participate.**
- **Margin of Preference will not be applicable.**

# REVISED TECHNICAL SPECIFICATIONS

| S/No | Technical Specifications | Compliance Sheet<br>To be completed by the Bidder with the required "Relevant Information", duly signed and submitted with the Bid. |
|---|---|---|
| 1 | PPE consistency of overall with Hood and Boot covers **(Large)**<br><br>**a. Disposable Protective Boot Cover**<br><br>Product parameters<br>Made from micro porous laminate material Colour light blue /light green/ grey<br>Elastic around the ankle for protection against contaminants and enhanced fit<br>Should be Antistatic treated<br>Sole and upper constructed of the same material Should be smooth<br>Elastic should be well stitched to the rim of the product<br>Full Elastic round the whole rim. Nonsterile<br><br>Large Length 42cm Width 18cm<br><br>Packaging parameters<br><br>Should be packed in multiples of 10's to make 100 in a primary pack with Standard weight of carton 15-20kg during the final delivery to warehouse<br>Labelling parameters:<br>Labelling should be in English.<br>Legible and in indelible ink and not on a stick on.<br>The primary, secondary and tertiary package should be labelled "GOK/MOH"<br>with manufacturers name and address,<br>Country of origin, Batch No, Date of manufacture and Expiry. (GOH/MOH markings MUST be done at pre delivery and full consignment).<br>Each carton to be clearly marked with the name and characteristics of the article and number of units per carton.<br>Should conform to KEBS / ISO standard or equivalent. Manufacturer must be KEBS / ISO certified or equivalent.<br>Submission of sample:<br>Submit a pack of 10 pieces of each size for evaluation. | |

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| | **b. Overall with Hood/ Coverall, protection, General Description**<br>Liquid-tight biohazard-protective coverall, for use in EVD patient-isolation units for infection prevention and control against viral penetration<br>Size<br>Medium<br>Large<br><br>Product Specifications Elasticated hood around face. Elasticated cuffs and ankles.<br>Sleeves with elasticated thumb loop.<br><br>Protective seams providing barrier equal to fabric.<br>Zipper with re-sealable flap protecting leakage through seams.<br>Each coverall has a stitched-in neck label indicating the type and performance of the suit against the below mentioned standards.<br>Colour: White/ yellow/orange<br>Material: Lightweight, do not contain rubber/ latex.<br>Antistatic treated on both sides.<br>Fabric is Infective agent tested against viral penetration at minimum 1.75kPa<br>Non-sterile<br>Single Use, disposable<br><br>Quality Standards<br><br>Conforms to:<br>European Directive 89/686/EEC on personal protective equipment Category III: Chemical protective coverall, Type 4 comply with EN14605:2005+A1:2009 (or equivalent) marketing approval certificate.<br>Barrier to infective agent standards: EN 14126:2003 certified passing infectious agent test according to ISO 16604:2004 (Resistance to penetration by blood-borne pathogens using bacteriophage Phi-X 174) standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)<br><br>Performance requirement ISO standards:<br>EN 340 – General requirements<br>EN ISO 17491-4 (EN 468) – Spray aerosol test method EN 14325 – Test methods & performance classification EN ISO 3758 – Textile care symbols<br>EN 12941 – Respiratory protective devices – powered filtering devices<br>EN 31092 – Determination of physiological properties – thermal and water- vapour resistance | |

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| | Packaging and labelling:<br><br>Individually packaged in a transparent plastic bag. Supplied with supplier's instruction for use.<br>All labelling must be in English<br>The primary and tertiary package should be labelled<br>"GOK/MOH" in bold letters (6" size minimum)<br>Labelling on primary packaging must include:<br>Manufacturer's name and address Country of origin<br>Name and/or trademark of the manufacturer<br>Batch No, Date of manufacture and Expiry Manufacturer's product reference<br>Type of product and main characteristics Instructions for disposal<br>Type and performance testing information against the mentioned standards.<br>Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol)<br>Information for handling, if applicable (or equivalent harmonised symbol)<br>Labelling on the secondary packaging unit: Labelling to be the same as primary packaging<br>Extra information required: Number of units per box | |
| **2.** | PPE consistency of overall with Hood and Boot covers **(Medium)**<br><br>**a. Disposable Protective Boot Cover**<br><br>Product parameters<br>Made from micro porous laminate material Colour light blue /light green/ grey<br>Elastic around the ankle for protection against contaminants and enhanced fit<br>Should be Antistatic treated<br>Sole and upper constructed of the same material Should be smooth<br>Elastic should be well stitched to the rim of the product<br>Full Elastic round the whole rim. Nonsterile<br><br>Medium Length 40cm Width 15cm<br><br>Packaging parameters<br><br>Should be packed in multiples of 10's to make 100 in a primary pack with Standard weight of carton 15-20kg during the final delivery to warehouse | |

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| | Labelling parameters:<br>Labelling should be in English.<br>Legible and in indelible ink and not on a stick on.<br>The primary, secondary and tertiary package should be labelled "GOK/MOH"<br>with manufacturers name and address,<br>Country of origin, Batch No, Date of manufacture and Expiry. (GOH/MOH markings MUST be done at pre delivery and full consignment).<br>Each carton to be clearly marked with the name and characteristics of the article and number of units per carton.<br>Should conform to KEBS / ISO standard or equivalent. Manufacturer must be KEBS / ISO certified or equivalent.<br>Submission of sample:<br>Submit a pack of 10 pieces of each size for evaluation.<br><br>**b. Overall with Hood/ Coverall, protection, General Description**<br>Liquid-tight biohazard-protective coverall, for use in EVD patient-isolation units for infection prevention and control against viral penetration<br>Size<br>Medium<br>Large<br><br>Product Specifications Elasticated hood around face. Elasticated cuffs and ankles.<br>Sleeves with elasticated thumb loop.<br><br>Protective seams providing barrier equal to fabric.<br>Zipper with re-sealable flap protecting leakage through seams.<br>Each coverall has a stitched-in neck label indicating the type and performance of the suit against the below mentioned standards.<br>Colour: White/ yellow/orange<br>Material: Lightweight, do not contain rubber/ latex.<br>Antistatic treated on both sides.<br>Fabric is Infective agent tested against viral penetration at minimum 1.75kPa<br>Non-sterile<br>Single Use, disposable<br><br>Quality Standards | |

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| | Conforms to:<br>European Directive 89/686/EEC on personal protective equipment Category III: Chemical protective coverall, Type 4 comply with EN14605:2005+A1:2009 (or equivalent) marketing approval certificate.<br>Barrier to infective agent standards: EN 14126:2003 certified passing infectious agent test according to ISO 16604:2004 (Resistance to penetration by blood-borne pathogens using bacteriophage Phi-X 174) standard at minimum exposure pressure of 1.75kPa (class 2) (or equivalent international standard)<br><br>Performance requirement ISO standards:<br>EN 340 – General requirements<br>EN ISO 17491-4 (EN 468) – Spray aerosol test method EN 14325 – Test methods & performance classification EN ISO 3758 – Textile care symbols<br>EN 12941 – Respiratory protective devices – powered filtering devices<br>EN 31092 – Determination of physiological properties – thermal and water- vapour resistance<br><br>Packaging and labelling:<br><br>Individually packaged in a transparent plastic bag. Supplied with supplier's instruction for use.<br>All labelling must be in English<br>The primary and tertiary package should be labelled<br>"GOK/MOH" in bold letters (6" size minimum)<br>Labelling on primary packaging must include:<br>Manufacturer's name and address Country of origin<br>Name and/or trademark of the manufacturer<br>Batch No, Date of manufacture and Expiry Manufacturer's product reference<br>Type of product and main characteristics Instructions for disposal<br>Type and performance testing information against the mentioned standards.<br>Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol)<br>Information for handling, if applicable (or equivalent harmonised symbol)<br>Labelling on the secondary packaging unit: Labelling to be the same as primary packaging<br>Extra information required: Number of units per box | |
| **3.** | **Apron Disposable**<br>Single-use straight sleeveless protective apron, for use in healthcare settings Seamless liquid proof and stain resistant<br>Comfortable to wear, apron has back- and neck-band strips attached (4 in total) | |

<table>
<tr><td></td><td>Both back- and neck-band can be adjusted/fastened Color: white<br>Material: polyethylene (PE) or biodegradable or compostable material Size: 85 x 145 cm (w x l) (+/- 15%)<br>Thickness, at not less than: 50 um<br>Can resist water and disinfectant (ethanol 70% and chlorine solution 0.05% or 500ppm)</td><td></td></tr>
<tr><td>4.</td><td>Gloves Examination, Disposable, Latex Size<br>Medium size<br>Product parameters:<br>Gloves, examination<br>Latex material Non – powdered Hypoallergenic<br>The gloves to have straight fingers Finger thickness single wall – 0.15mm Palm thickness single wall – 0.12mm<br><br>Cuff thickness single wall – 0.08mm<br>Tensile strength minimum 18Mpa before aging and 14Mpa after ageing Elongation percentage (%) – 650% before ageing and minimum<br>500% after ageing Modulus 500% - 5.5Mpa<br>Force at break (N) – minimum 9N before ageing and minimum 6N after ageing. Protein content – maximum 200µg/dm2.<br>Powder level maximum 10mg/dm2 Accommodates pressure of 22kPa ±5kPa The powder must be adequate.<br>Cuff termination must be in the form of rolled rim. Disposable<br>Non-sterile but clean<br>Glove has a firm and fitting cuff<br>The cuff should not tear off when applied over raglan sleeves Glove is watertight (accommodates 1000cm3 of water).<br>Airtight<br>Gloves closely fit the morphology of the hand Should not have hard masses Should not tear easily while gloving Should not leak<br>Weight and Volume: Estimated weight: 0.070 kg Estimated volume: 0.400 cdm<br>Glove Dimensions and Tolerances<br><br>
<table>
<tr><td rowspan="3">SIZE</td><td></td><td>MINIMUM</td><td>MAXIMUM</td><td>MINIMUM</td></tr>
<tr><td>WIDTH</td><td>LENGTH</td><td>THICKNESS</td><td>THICKNESS</td></tr>
<tr><td>(mm)</td><td>(mm)</td><td>(mm)</td><td>(mm)</td></tr>
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|---|---|---|---|---|---|
| | | | | Smooth | Smooth |
| | | | | area 0,08 | area 0,22 |
| | | | | Textured | Textured |
| Medium | 95±10 | 230 | | area 0,11 | area 0,23 |

Packaging parameters:
Should be packed in boxes of 50 Pairs
Standard weight of carton 15-20kg during the final delivery to warehouse
Labelling parameters:
Labelling should be in English
Legible and in indelible ink and not on a stick on

The primary, secondary and tertiary package should be labelled "GOK/MOH" with manufacturers name and address, Country of origin, Batch No, Date of manufacture and Expiry date
Each carton to be clearly marked with the name and characteristics of the article and number of units per carton Should conform to KEBS / ISO standards or equivalent Manufacturer must be KEBS / ISO certified or equivalent
Submission of sample:
Submit a sample of one (1) box for evaluation.

**5.** Personal Protective Equipment — Face shield — Specification

1 Scope
This Kenya Publicly Available Specification prescribes the minimum requirements, test methods and use of locally manufactured face shield for use by health care service providers during the COVID-19 pandemic or any other emergency declared by the Cabinet Secretary concerned with Health at the time.

2 Normative references
The following referenced documents referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.
ASTM D1003-13, Standard Test Method for Haze and Luminous Transmittance of Transparent Plastics

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| | KS ISO 4007, Personal protective equipment — Eye and face protection — Vocabulary<br>KS ISO 18526, Eye and face protection — Test methods — Part 4: Headforms<br><br>3 Terms and definitions<br>For the purposes of this document, the terms and definitions given in KS ISO 4007 and the following apply.<br>3.1<br>face shield<br>personal protective equipment covering the eyes and all, or a substantial part, of the face, which can be mounted directly on the head using a frame or headband and/or straps for use by health care workers in Kenya during the COVID-19 pandemic or any other emergency declared by the Cabinet Secretary concerned with Health at the time.<br>3.2<br>Frame<br>structure of the face shield on which the oculars/lens(s) are mounted<br>3.3<br>lens/visor/screen<br>a protective component of the face shield through which the wearer sees<br>3.4<br>plano lens<br>lens that does not incorporate a corrective prescription; this lens is not necessarily flat<br><br>4 Requirements<br>4.1 General<br>4.1.1 Face shield manufacturers shall have a risk management system in place, including policy and risk management file.<br>4.1.2 Face shields shall satisfy all applicable requirements and unless otherwise stated, all values for measurements shall be considered as nominal.<br>4.1.3 The face shield shall either be single-use or reusable. Reusable face shields shall be made of material that can be cleaned and disinfected, and if single-use, the material shall be disposable.<br>4.2 Construction<br>Face shields shall be constructed such that either it has a non-removable visor/lens or removable ones. The non-removable type of construction shall have a homogeneous and continuous lens or visor and frame and the lens/visor shall not be removed from the frame/headband without damage to the device. Removable type of construction shall be fabricated to have lens/visor removed and all shall fit a single frame or head-harness. When won, the face shield shall fit on the head snugly.<br>4.3 Optical requirements | |

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| | 4.3.1 Optical quality<br>Face shields shall be free of striae, bubbles, waves and other visible defects which would impair the wearer's vision.<br>The visor/lens/shield shall have a minimum thickness of 0.25 mm sheets of acetate, Mylar, PET mpolycarbonate, or any type of clear plastic film.<br>The surface of the visor/lens shall be scratch resistant and should not be prone to scuff marks.<br>4.3.2 Haze and luminance transmittance<br>When tested in accordance with ASTM D1003-13, clear plano lenses/visor/ocular shield shall not exhibit more than 3% haze.<br>4.4 Physical requirements<br>Face shields shall be free from projections, sharp edges or other defects, which are likely to cause discomfort or injury during use.<br>4.4.1 Minimum coverage area<br>Completely covers the sides and length of the face.<br>The minimum overall width and length of the face shield shall be 290 mm and 210 mm, respectively.<br>The shields, including the frame and/or lens/visors shall cover in plain view an area of not less than 40 mm in width and 33 mm in height (elliptical) in front of each eye, centred on the pupil centres of the test headform as<br>shown in Figure 1 (a) and (b).<br>**NB: Eligible to Local Manufacturers only** | |
| **6.** | Mask, particulate respirator (N95) General Description:<br>Respirator masks protecting against airborne pathogens. Anti-penetration high filtration mask<br>Product Specifications<br>Material: non-woven filter layer<br>Filtration level: > 95 % for particles from 0.1 to 0.3 micron Air permeability: > 2 mm H2O<br>Shape of the mask: duckbill, folded (horizontal) width-wise Without valve<br>Respirator mask fits all face shapes, without inspiration/expiration air-leakage<br>Upper edge has integrated easy malleable nose bridge strip reducing fogging of protective eyewear<br>Size nose bridge strip: 4 x 90 mm (w x l) (+/-10%)<br>Two pre-attached elasticated straps, fitting (i) around top of the head, (ii) around base of the head<br><br>Colour: white Non-sterile<br>Single use, disposable<br>Each mask bares clear identification of<br>- protection provided FFP2/N95,<br>- which side to wear up (nose),<br>- manufacturer's name, and | |

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| | - model reference<br>Quality Standards<br>Respirator mask conforms to standards:<br>NIOSH N95 recommended by the CDC and WHO for healthcare workers. The disposable respirator should be marked with the manufacturer's name, the part number (P/N), the protection provided by the filter (e.g., N-95), and "NIOSH."<br>Or<br>EN 149: 2001/FFP2. The disposable respirator should be marked with the manufacturer's name, EN 149: 2001/FFP2 and CE certification number.<br>Packaging and labelling:<br>Packaging: 10 pcs. / Bag<br>Standard wt. of carton 15-20kg during final delivery to the warehouse All labelling must be in English<br>The primary and tertiary package should be labelled "GOK/MOH" in bold letters (6" size minimum)<br>Labelling on primary packaging must include:<br>- Manufacturer's name and address<br>- Country of origin,<br>- Name and/or trademark of the manufacturer<br>- Batch No, Date of manufacture and Expiry<br>- Manufacturer's product reference<br>- Type of product and main characteristics<br>- Type and performance testing information against the mentioned standards<br>- Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonised symbol)<br>- Information for handling, if applicable (or equivalent harmonised symbol)<br><br>Labelling on the secondary packaging unit: Labelling to be the same as primary packaging<br>Extra information required: Number of units per box | |

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| 7. | Mask, medical (Surgical masks 3-ply) Product Parameters:<br>Surgical masks are made from non-woven cellulose material plus filter paper.<br>Top layer 25gsm spun bonded polypropylene, Middle layer 25gsm melt blown polypropylene and third layer25gsm spun bonded polypropylene.<br>Shape – rectangular in shape. Measurements – Width - 10cm Length – 19cm Must be 3 ply<br>Should have folds in the middle of 1.5cm in width<br>Should have four straps from each of the four corners of 42cm each Sky blue/light green in colour<br>Should have a nose bridge<br>Provide technical data from a recognized lab to confirm the above. Top layer Waterproof<br>Breathable<br>Packaging Parameters:<br>In a box of 50 Pieces.<br>Standard weight of carton 15-20kg during final delivery to the warehouse.<br>Labelling Parameters:<br>Labelling should be in English.<br>Legible and in indelible ink and not on a stick on.<br>The primary, secondary and tertiary package should be labelled<br>"GOK-MOH" with manufacturers name and address, Country of origin, Batch<br>No, Date of manufacture and Expiry<br>Each carton to be clearly marked with the name and characteristics of the article and number of units per carton.<br>Should conform to KEBS / ISO standard or equivalent. Manufacturer must be KEBS / ISO certified or equivalent<br>Submission of sample:<br>Submit a sample of one pack (50 pieces) for technical evaluation<br>**NB: Eligible to Local Manufacturers only** | |