

KENYA MEDICAL SUPPLIES AUTHORITY

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All Correspondence should be addressed to Chief Executive Officer

When replying please quote our ref:

KEMSA/ GF-PROC/HIV/2024(025)

Date: 15<sup>th</sup> February, 2024

ADDENDUM 1

Attn.: All Prospective Bidders

RE: TENDER NO.: GF ATM HIV NFM- 2023/2024 OIT – 019 FOR SUPPLY OF MALE  
CONDOMS

Pursuant to ITT Clause 8, At any time prior to the deadline for submission of Tenders, the Procuring Entity may amend the tendering document by issuing an addenda. Any addendum issued shall be part of the tendering document and shall be communicated in writing to all who have obtained the tendering document from the Procuring Entity in accordance with ITT 6.


In view of the above;

- 1) Attached find revised Technical Specifications.
- 2) Bidders are notified that the closing date for the tender has been extended as indicated below:

Initial Tender Closing Date	New Tender Closing Date
22 <sup>nd</sup> February,2024 At 10:00am	29 <sup>th</sup> February, 2024 At 10:00am
Bid bond Validity Period will therefore start running from new closing date.	

- 3) Other terms and conditions provided in the tender document remain the same.

Yours faithfully,

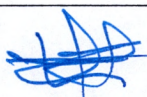
  
Edward Buluma  
Ag. Director, Procurement  
FOR: CHIEF EXECUTIVE OFFICER





## Technical Specifications for Male Condoms

General Specifications	MOH Specifications
Evidence of WHO/UNFPA Prequalification	Mandatory
Evidence of ISO 13485	Mandatory (ISO Quality systems approval / Certificates)
Product specific specifications	<ul style="list-style-type: none"> <li>• Colour; Natural and transparent colour, as per prequalification criteria</li> <li>• Texture; Dotted</li> <li>• Straight and parallel sided</li> <li>• Reservoir tip</li> <li>• Shelf life of 5 years</li> <li>• Labelling and package inserts shall be in English</li> <li>• <b>Shelf life:</b> Upon the date of receipt to the warehouse, the product should have a minimum of 75% remaining shelf-life.</li> </ul>
Secondary Packaging	Box to contain 144 pieces
Length	Greater or equal to 180 mm (condoms with widths from 50.0 mm up to 55.5 mm).
Width	53 mm, with a tolerance of $\pm 2$ mm
Thickness	Single wall thickness: 0.065 $\pm$ 0.015
Lubricant quantity	<p>Lubrication: lubricated with a quantity of silicone fluid in accordance with ISO 2859-1 Inspection Level S-2</p> <p>The quantity of lubricant, including powder, in the package should be (550 <math>\pm</math> 150) mg.</p>





General Specifications	MOH Specifications
<b>Packaging</b>	<ul style="list-style-type: none"> <li>• 1 piece packed in a square aluminium foil (56 mm x 56 mm) <math>\pm</math> 2 mm, Strip size of 3 pieces</li> <li>• Each latex condom individually sealed in foil laminate, which will bear an approved GOK logo and clearly marked 'GOK – Not for sale', 'Dotted'</li> <li>• 144 pieces of condoms (48 strips) packed in a plastic bag before placing in secondary packaging/gross box.</li> <li>• 50 secondary packages/gross boxes packed per shipping carton</li> </ul>
<b>Labelling of Secondary packaging</b>	<ul style="list-style-type: none"> <li>• LOT identification number</li> <li>• Month and year of manufacture; Year should be written as four-digit number and month as a two-digit number</li> <li>• Month and year of expiry; Year should be written as four-digit number and month as a two-digit number</li> <li>• Manufacturer's name and registered address</li> <li>• Nominal width of condom expressed in millimeters</li> <li>• Number of condoms in the box</li> <li>• Instructions for storage</li> </ul>
<b>Labelling of cartons</b>	<ul style="list-style-type: none"> <li>• Lot identification number</li> <li>• Month and year of manufacture; Year should be written as four-digit number and month as a two-digit number</li> <li>• Month and year of expiry; Year should be written as four-digit number and month as a two-digit number</li> <li>• Manufacturer's name and registered address</li> <li>• Nominal width of condom expressed in millimeters</li> <li>• Number of condoms contained in the carton</li> <li>• Shipping carton clearly labeled: <b>GOK-MOH-NOT FOR SALE, DOTTED</b></li> <li>• <b>GOVERNMENT OF KENYA –MINISTRY OF HEALTH</b></li> </ul>
<b>Registration requirements</b>	<ul style="list-style-type: none"> <li>• Medical devices/product should have a registration certificate/license from Regulatory authority in the country of Origin and</li> <li>• Must be listed by the Kenya Pharmacy and Poisons Board (PPB) as a medical device. Bidders MUST attach valid listing certificate from PPB.</li> </ul>
<b>Additional requirements</b>	<ol style="list-style-type: none"> <li>i) Instructions insert including instructions on disposal of used condom (s).</li> <li>ii) A statement that the condom is for single use ONLY.</li> <li>iii) The number of the International Standard, i.e. ISO 13485.</li> </ol>

General Specifications	MOH Specifications
<b>Artwork</b>	<ul style="list-style-type: none"> <li>• 'SURE' logo on the foil, 'GOK-Not for Sale on the foil: DOTTED on the foil.</li> <li>• The art work shall be provided by the National AIDs and STI Control Program (NASCOP).</li> <li>• The production of specialized art work shall be subject to proof reading and approval of the final proofs by NASCOP.</li> </ul>





