

KENYA MEDICAL SUPPLIES AUTHORITY

National Supply Chain Centre,
Airport North Road, Embakasi,
P.O. Box 47715 - 00100,
Nairobi, Kenya.



Tel: +254 719 033000, +254 111 035 800
Email: info@kems.go.ke

All Correspondence should be addressed to Chief Executive Officer

When replying please quote our ref:

KEMSA/GF-PROC / TB - RSSH ONT 02/24-25

Date: 20th March, 2025

CLARIFICATION 2

ATTN.: ALL PROSPECTIVE BIDDERS

TENDER NO.: GF-ATM-TB-RSSH-C19RM- 2024/2025 - ONT 02 - SUPPLY OF COMMUNITY HEALTH PROMOTERS' KITS

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

Question 1

Clarification Regarding Technical Evaluation Requirements (B. Technical Evaluation (ii) - Non-Pharmaceutical Laboratory Products):

We have carefully reviewed the requirements outlined in points (c) under "Non-Pharmaceutical/Laboratory Products" and wish to seek clarification on the following:

Point (c): This point mandates "Provide current and valid manufacturing Certificate of Quality (ISO 13485) by an independent recognized body to the manufacturer for *Digital Thermometer, Glucometer, BP machine and weighing scale*. The certificate must be item specific (MANDATORY)."

We recognize the necessity of ISO 13485 certification for medical devices such as *digital thermometers, glucometers, and BP machines*. However, we respectfully point out that a *weighing Scale*, as commonly understood and used in this context, is not typically classified as a medical device. Therefore, obtaining an ISO 13485 certification for a weighing scale is often not applicable.

Request: We kindly request that the requirement for ISO 13485 certification be specifically applied to the medical devices listed (*Digital Thermometer, Glucometer, and BP machine*) and that the *weighing scale* be excluded from this mandatory requirement.

Response

The weighing scale requires KEBS certificate.

Yours faithfully,

Moses Sudi

Procurement Director

FOR: CHIEF EXECUTIVE OFFICER