

PUBLIC NOTICE



CLARIFICATION ON MEDICAL DEVICES AND LABORATORY EQUIPMENT CURRENTLY OUT OF REGULATORY SCOPE FOR IMPORT CONTROL

The Botswana Medicines Regulatory Authority (BoMRA) wishes to inform all stakeholders, clearing agents, and port of entry authorities regarding the current regulatory scope for medical devices and related equipment under the Medicines and Related Substances Act (MRSA).

To facilitate smooth cross-border trade and prevent unnecessary delays at points of entry, BoMRA clarifies that the product categories listed below are currently OUT OF REGULATORY SCOPE and DO NOT require BoMRA import clearance, permits, or registration prior to entering Botswana:

1. INDUSTRIAL USE: PPE intended strictly for industrial, occupational safety, or non-medical environments (e.g., industrial safety helmets, heavy-duty gloves, non-medical masks, industrial respirators).

2. EXTERNAL QUALITY ASSESSMENT (EQA) & PROFICIENCY TESTING MATERIALS: Calibration standards, reference materials, and proficiency testing panels used strictly in laboratory quality assurance to validate and verify analyzer performance.

3. GENERAL LABORATORY EQUIPMENT (NON-CLINICAL USE): General apparatus and equipment (e.g., beakers, pipettes, measuring cylinders, centrifuges) utilized in educational institutions, universities, water utility laboratories, and non-health settings that are not intended for clinical diagnostic purposes.

4. MEDICAL DEVICES INCLUDING IVDS FOR STUDIES & EDUCATIONAL PURPOSES: devices solely for academic, training, or experimental use in universities and schools.

5. MEDICAL TRAINING EQUIPMENT & SIMULATORS: Educational models, training devices, and anatomical simulators (e.g., artificial training lungs, CPR manikins) used for academic and training instruction.

6. GENERAL WELLNESS & FITNESS DEVICES: Products intended solely for general wellness, fitness tracking, or lifestyle monitoring used by individuals (e.g., smartwatches, pulse monitors for sports/jogging, body composition scales, and general fitness monitors) that are not intended for clinical diagnosis, disease prevention, or hospital treatment.

7. BREATHALYZERS & SCREENING EQUIPMENT: Alcohol breathalyzers, roadside sobriety testing units, workplace alcohol screening tools, along with their associated accessories, calibration gases, and consumables, provided they are not intended for clinical or hospital diagnostic procedures.

8. SPARE PARTS & ACCESSORIES FOR MEDICAL DEVICES: Replacement components, maintenance hardware, and spare parts imported for the repair or servicing of existing equipment.

9. FORENSIC/LAW-ENFORCEMENT TEST KITS: Tests intended only for law enforcement or other non-medical purposes (e.g., certain drug-abuse tests used solely in forensic settings).

Consignments containing only items listed above must be granted import clearance without requiring BoMRA import permits or clearance letters. This exemption reflects the current phase of regulatory implementation. BoMRA reserves the right to incorporate any of these categories into active regulatory oversight in the future. Any changes to the regulatory scope will be formally communicated through an official public notice prior to enforcement.

For further regulatory inquiries, please contact the Medical Devices Unit at medicaldevices.services@bomra.co.bw or call +267 373 1720.