Regulatory Body: Botswana Medicines Regulatory Authority (BoMRA)
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BOMRA Medical Devices including IVDs Regulatory Update.

BOMRA Medical Device Regulatory Strategy (2022–2030) Advancing Botswana from WHO GMRF "Basic Level of Control" to "Expanded Level" of Control

1. Strategic & Legislative Evolution
Botswana is transitioning from a basic oversight model to a comprehensive, globally aligned lifecycle regulatory framework.

Strategy Phase	Legal Framework	GMRF Level	Strategic Focus
2022 – 2025	**MRSA 2013**	**Basic**	Legal provisions, guidelines, processes, listing of devices & MD Establishments, classification and foundational market entry rules.
2026 – 2030	**MRSA 2025**	**Expanded**	**Comprehensive Regulation:** Mandatory registration, Licensing, inspections, retentions, active surveillance, and technical verification.

2. Global Harmonization & Convergence
BoMRA ensures patient safety and trade facilitation through official membership in global regulatory forums:
- **IMDRF:** Affiliate Member (Joined September 2024).
- **GHWP:** Full Member (Endorsed December 2024).

3. Mandatory Registration & Variations Roadmap
Registration deadlines are based on risk class. Once a deadline passes, the device is removed from the Listing Register and must be in the Registration Register.

Device Risk Class	Registration Start	Mandatory Deadline	Registration Status
Class C & D (High)	**April 2024**	**June 30, 2026**	**Active (Closing Soon)**
Class B (Moderate)	**April 1, 2026**	**March 31, 2027**	Scheduled
Class A (Low/ Notification)	**October 1, 2026**	**September 30, 2027**	Scheduled
Variations	**April 2025**	Ongoing	**In Effect**

Critical Note: Annual Retention Fees must be paid for both listed and registered devices. Failure to pay by the anniversary date will result in immediate removal from the register.
Registration done via BOMRA Regulatory Information Management Systems (BRIMS). Applicants should be Manufacturers (local or international) or Authorized Representatives. If Applicant is not a Local Entity, a Local Technical Representative (LTR) need to be appointed.
Regulatory guidelines: https://www.bomra.co.bw/downloads/#51-55-wpfd-guidelines-manuals

4. Establishment Licensing & Trade Controls
A key milestone of the 2025 transition is the shift from "listing" to "licensing" for all local MD business entities.
- **Licensing of MD Establishments:** Effective April 1, 2025, the system transitioned from Listing of Establishments to formal **Licensing.** All local manufacturers, wholesalers, importers, and distributors must hold a valid BoMRA license.
- **Import/Export Permits:** Commencing **April 1, 2025**, mandatory permits and import fees are required for every consignment of medical devices and IVDs entering or leaving Botswana via the **BRIMS** portal - https://brims.bomra.co.bw/#/public/login
- **Local Quality Audits:** Scaling of mandatory on-site audits to verify GWP and ISO compliance for all licensed establishments.

5. 2026–2030 Programmatic Activation
BoMRA will be developing and implementing the following lifecycle programs:
- **National PMS & Vigilance:** systematic field sampling and adverse event reporting.
- **Laboratory Testing:** development of protocols for physical technical verification.
- **Clinical Trial (CT) Plans:** structured oversight for all device investigations.
- **Stakeholder Consultation:** Drafted BOMRA Medical Device Regulations (BOMRA MDR 2026) for the **MRSA 2025** are currently open for feedback to finalize implementation.