

UPDATE OF THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES IN SENEGAL

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NATIONAL CONTEXT

Although medical devices are essential for patient care, they remain health products that are still poorly known and often complex. Their effective use requires rigorous management, guaranteed by appropriate legislative and regulatory texts.

In Senegal, only IVDs (in vitro diagnostic medical devices), particularly laboratory reagents, were until recently covered by a regulatory framework. Indeed, these products have been regulated since **Decree No. 2009-365 of April 20, 2009**, which sets the conditions for registration and wholesale distribution of laboratory reagents.

For other classes of medical devices, there was until then a legal vacuum. Thus, on **June 24, 2022**, the **WAEMU Commission** adopted **Decision No. 03/2022/CM/UEMOA**, adopting guidelines for the harmonization of medical device regulation within WAEMU Member States.

HISTORIC

The decrees and orders of 2009 only regulated in vitro diagnostic devices. Other types of medical devices were not covered.

There was no clear mandate for the national pharmaceutical regulatory authorities under this framework, nor a classification system for medical devices an essential element given their diversity.

CURRENT LEGAL FRAMEWORK (1/2)

DATE	Text
April 7, 2022	Decree No. 2022-824 establishing and setting the rules for the organization and operation of the Senegalese Pharmaceutical Regulatory Agency (ARP).
June 24, 2022	Decision No. 03/2022/CM/UEMOA adopting the guidelines on the harmonization of medical device regulation in WAEMU Member States.
June 13, 2023	Law No. 2023-06 of June 13, 2023, relating to medicines, other health products, and pharmacy.
December 27, 2023	Decree No. 2023-2419 of December 27, 2023, setting the conditions for the manufacture, registration, import, export, and distribution of medical devices.
« ? »	Order setting out the implementing provisions of Decree No. 2023-2419 on medical devices.

The new WAEMU regulation on medical devices defines the responsibilities of stakeholders, assigned to the **National Pharmaceutical Regulatory Authorities (NPRA)** of each Member State.

At both the WAEMU and national levels, the framework regulates:

- the classification of medical devices;
- the conditions for manufacture, import, export, and distribution;
- quality, safety, and performance requirements;
- post-market surveillance;
- the authorization of Class B, C, and D devices, and declaration for Class A devices;
- and the approval of establishments involved in manufacture, registration, import/export, and maintenance.

CLASSIFICATION

Classification of medical devices according to their level of risk.

class	Degree of risk
A	Low
B	Low-Middle
C	Middle-High
D	High

EVOLUTION OF REGULATORY FRAMEWORK IN SENEGAL

- **February 10, 2023:** Decision No. 00000494/MSAS/ARP/DAJ/SRP establishing regulatory reliance and/or unilateral recognition (without reciprocity) of certificates, reports, or decisions issued by other national pharmaceutical regulatory authorities (ANR).
- A guideline describing additional modalities for granting marketing authorizations (fast track, reliance, collaboration) for medicines and other health products, including medical devices.
- **September 22, 2023:** WHO CRP with accelerated registration of WHO-prequalified IVDs.
- Import authorizations for medical devices issued by ARP.

- Finalization of the regulatory framework (draft order);
- Effective implementation of the medical device regulation (authorization, market surveillance, establishment licensing);
- Creation of medical device production units as part of the national pharmaceutical industry revitalization plan;
- Achievement of maturity level 3 GBT+MD for Senegal according to the WHO evaluation tool.

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