For A Healthier Africa
AFRiSUMMIT
2nd - 5th November 2025
Hilton Grand Nile Hotel, Cairo - Egypt

CURRENT UPDATES IN UGANDA'S MEDICAL DEVICE REGULATORY FRAMEWORK

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REGULATORY FRAMEWORK

01

The NDA was founded in 1993 under the *National Drug Policy and Authority Act* (NDP&A Act)

02

The National Drug Policy and Authority Act (Cap 206 of the laws of Uganda), Regulations, Sections 64(g)

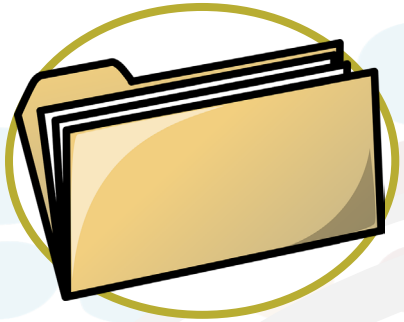
03

Statutory Instrument No. 29 of 2014, also referred to as *The National Drug Policy and Authority (Registration) Regulations, 2014*

04

Statutory Instruments No 77 of 2019 (Regulation of Surgical Instruments and appliances) to operationalize previous S.I

ACTIVITIES



RECENT DEVELOPMENTS

- Registration of medical devices started with surgical instruments and appliances being priority.
- Under the auspices of AUDA-NEPAD, joint assessment of monkey pox IVD done
- New fees regulation in place (The National Drug Policy and Authority Regulations, 2025)
- Foreign GMP audits begun
- Increase in number of local manufacturers
- Guidelines for PE of IVDs in the offing in a collaborative effort with CPHL (MOH)

UPCOMING ACTIONS AND PRIORITIES

- The National Drug and Health Products Authority Bill 2024. First reading done and stakeholder feedback sought.
- Mandatory registration of medical devices deadline of 20 February 2026
- Mandatory sampling and testing of selected medical devices.
- Participate in joint audit inspections regionally

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REGISTRATION OF MEDICAL DEVICES

Requirements for class A

- the completed application form (Appendix I);
- letter of authorisation for the Local Technical Representative (LTR);
- detailed information on the device;
- instructions for use (IFU), patient information leaflet and promotion materials, including brochures and catalogues;
- labelling information;
- information on sterilisation method(s) and validation standards used (where applicable);
- proof of a Quality Management System (QMS), for example a valid ISO 13485 certificate;

Requirements for classes B,C and D

- the completed application form (Appendix I);
- letter of authorisation for the LTR;
- Summary Technical Documentation (STED) Table of Contents;
- labelling information;
- evidence of conformity to the Essential Principles/Essential Requirements Checklist (Appendix II) of the guidelines;
- proof of a QMS, for example a valid ISO 13485 certificate;
- two physical samples of the product, where applicable.

REGISTRATION OF MEDICAL DEVICES

- a Certificate of Free Sale;
- two physical samples of the product, where applicable.

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