

Decision of the Chairman of the Authority No. (239) of 2026

Chairman of the Egyptian Drug Authority,

Having reviewed:

- Law No. 127 of 1955 regulating the practice of the pharmacy profession;
- Law No. 151 of 2019 establishing the Egyptian Drug Authority;
- Presidential Decree No. 28 of 2026 concerning the formation of the Board of Directors of the Egyptian Drug Authority;
- EDA Chairman's Decision No. 343 of 2021 issuing the Rules for the Registration of Biological Products;
- EDA Chairman's Decision No. 122 of 2022 concerning the Listing and Marketing of Cosmetic Products;
- EDA Chairman's Decision No. 146 of 2022 concerning the Rapid Alert, Recall and Ban System for Human and Biological Medicinal Products;
- EDA Chairman's Decision No. 425 of 2022 approving the Policy and Procedures Governing Batch Release of Biological Products;
- EDA Chairman's Decision No. 783 of 2022 regulating sampling and testing procedures;
- EDA Chairman's Decision No. 444 of 2023 concerning importation, release and customs clearance procedures;
- The proposal submitted by the Head of the Central Administration for Inspection of Pharmaceutical Establishments;
- And for the interest of work;

(Article 1)

The provisions of Decision No. 783 of 2022 shall apply to biological products, medical devices in vitro diagnostic reagents and cosmetic products. The Central Administration for Inspection shall conduct random sampling in factories during product validity.

(Article 2)

The regulatory guideline issued under Decision No. 783 of 2022 shall be updated to include sampling and Testing procedure for registration and post registration phases, Actions required to be taken in response to non compliance issued for batches tested by central administration of drug control, and other necessary updates in accordance with Relevant laws & regulations.

(Article 3)

This Decision shall enter into force as of the date of its issuance. Any contrary provisions are repealed. The competent authorities shall implement this Decision

Chairman of the Egyptian Drug Authority

Dr. Ali El Ghamrawy

Issued on: 30/4/2026