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

Medical Device Regulation in Tunisia

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ANMPS
الوكالة الوطنية للدواء و مواد الصحة
AGENCE NATIONALE DU MÉDICAMENT ET DES PRODUITS DE SANTÉ
NATIONAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS

Introduction and Background

- Medical Devices (MDs) and In Vitro Diagnostic Medical Devices (IVDs) currently do not have specific Tunisian legal texts governing them (a draft law is under validation)

- Only imported products are subject to *Technical Import Control* (CTI) procedures in order to obtain *Marketing Authorization for Consumption* (AMC), in accordance with Law No. 94-41 of March 7th, 1994, related to foreign trade

- Locally manufactured products are monitored within the framework of *market surveillance* (complaints handling, materiovigilance)

Documentary review and sample control

- The control carried out by the National Medicines and Health Products Authority (ANMPS) consists of a documentary evaluation, with or without analytical testing, according to a predefined checklist

Documentary review references :

- Mainly based on European regulations, as well as American and Canadian standards

Sample Control :

- Verification of mandatory labeling, packaging integrity, and absence of foreign materials
- **Testing** :

✓ Physicochemical, mechanical, and microbiological analyses (applied to products such as gloves, needles, condoms, etc)

Check list

Certificate of Origin

Issued by the Chamber of Commerce in the country of origin and linked to the corresponding invoice.

Invoice

Indicating the batches of the products included in the application.

Certificate of Free Sale

Issued by a competent authority in the country of origin

ISO 13485 Quality Management System Certificate

Required for Class I medical devices

Certificates: Sterilization Biocompatibility

As indicated by the sterilization pictogram on the product labeling.

Manufacturer's Declaration of Conformity

Issued in compliance with Directive 93/42/EEC or the EU Medical Device Regulation (MDR 2017/745).

CE Certificate in accordance with MDR 2017/745 – valid, or, if issued under the Directive and expired, accompanied by a confirmation letter.

Transitional Measures in Tunisia

- **Tunisia has issued two successive official notes regarding transitional measures**

- **First note: January 26th, 2023: AMCs were granted only to medical devices with at least 3 years of presence on the Tunisian market that hold a valid approval from a competent authority or valid MDD certificates at the time of their manufacture.**

- **Second note: October 30th, 2023: Tunisia adopted Regulation (EU) 2023/607, amending Article 120 of Regulation (EU) 2017/745 (MDR).**
  At that point, manufacturers were required to provide proof of a signed agreement with a Notified Body responsible for MDR conformity assessment.

Procedure for Obtaining the Marketing Authorization for Consumption (AMC)

- Marketing Authorizations for Consumption (AMC) are granted for each batch of imported medical devices
- Since June 2025, the evaluation of technical documentation and sample inspection has been conducted every two years only (administrative AMC)
- Currently, most medical devices that are subject to control by the National Medicines and Health Products Authority (ANMPS) are sterile (The others are either freely importable or controlled by other departments of the Ministry of Health)
- In the near future, in vitro diagnostic medical devices (IVDs) and medical equipment will also fall under the Agency's responsibility

Draft Legislation on Medical Devices in Tunisia

- **Single Regulatory Text** for Medical Devices (MDs) and In Vitro Diagnostic Medical Devices (IVDs)
- **Registration**: Economic operators / MDs & IVDs
- **Manufacturing**: Granting of operating licenses following a favorable inspection report (with strong emphasis on Quality Management Systems – QMS)
- Establishment of a **Technical Committee** for MDs and IVDs, consisting of multidisciplinary experts

Draft Legislation on Medical Devices in Tunisia

- **Import, distribution, and sales activities will be governed by a regulatory framework**
- **A traceability system for medical devices (MDs) and in vitro diagnostic devices (IVDs) will be implemented by all economic operators and healthcare facilities**
- **Reinforced market surveillance and vigilance will be ensured through collaboration between the competent authority and economic operators**

Future Outlook and Regulatory Transition

- **The official publication date of the new Medical Device Law is not yet known.**
- **According to the current draft, a transitional period will be granted:**
  - **1 year for importers and imported medical devices,**
  - **2 years for local manufacturers, starting from the law's enforcement date.**
- **The registration of economic operators and medical devices will enable the Authority to identify all devices placed on the Tunisian market.**

Future Outlook and Regulatory Transition

The new AMC procedure, implemented in June 2025, has already reduced administrative burden:

The evaluation of technical documentation and sample inspection has been conducted every two years only (administrative AMC) :

- Ensuring continued safety and quality of medical devices,
- Serving as a transition step toward full registration.

Conclusion and outlook

- The regulatory framework for medical devices in Tunisia is undergoing significant reform
- This is reflected in the establishment of the National Agency for the Control of Medicines and Health Products, which will expand its scope to include in vitro diagnostic devices and medical equipment, as well as in the upcoming legislation that will enable the registration and traceability of all medical devices on the Tunisian market
- The competent authority aims to centralize and harmonize control procedures for all health products , improving efficiency, transparency, and consistency to the benefit of importers, foreign manufacturers, and regulatory authorities

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