

Procedures for the Market Placement of Medical Devices in Dosage Form Year 2026

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Table of Contents

Content	Page
1. Procedures for the Circulation of Medical Devices in Dosage Form	3
2. Workflow for Medical Devices in Dosage Form	5
3. Inquiry Requirements	6

I. Procedures for the Circulation of Medical Devices Submitted in Dosage Form

The evaluation process for applications regarding the circulation of medical devices in dosage form is conducted based on sterility (sterile or non-sterile) and medical device classification, as follows:

1. The following products:

- Sterile products in all their dosage forms.
- Non-sterile products in the following dosage forms: **Vaginal - Rectal - Buccal - Otic - Oral - Nasal.**
- For all medical device classification grades.

Procedures:

- Obtaining a registration license is required as an essential prerequisite for issuing an importation approval.
- For **Vaginal / Rectal** devices that previously received a circulation approval by a decision from the General Administration's Scientific Committee, dealers are committed to the following:
 - Reviewing the registration procedures via the link for the Regulatory Guide for the Registration Procedures of Imported and Local Medical Devices Holding International Quality Certificates (Section 4.2).
 - Submitting a **temporary registration file before July 31, 2026**; a circulation grace period of 6 months shall be granted from the date of file acceptance, during which the company shall prepare a complete registration file.
 - The registration file is to be completed, and an additional grace period of one year is granted from the date of file acceptance to complete registration procedures and obtain the notification.

2. Products in dosage forms other than those mentioned above, if the classification falls within: (Class IIa - Class IIb - Class III):

- Following the currently applicable procedures, the following shall be conducted:
 - Reviewing registration procedures via the aforementioned link (Section 4.2).
 - Submitting a temporary registration file; a circulation grace period of 6 months is granted from the date of file acceptance, during which the company prepares a complete registration file.

Central Administration of Medical Devices

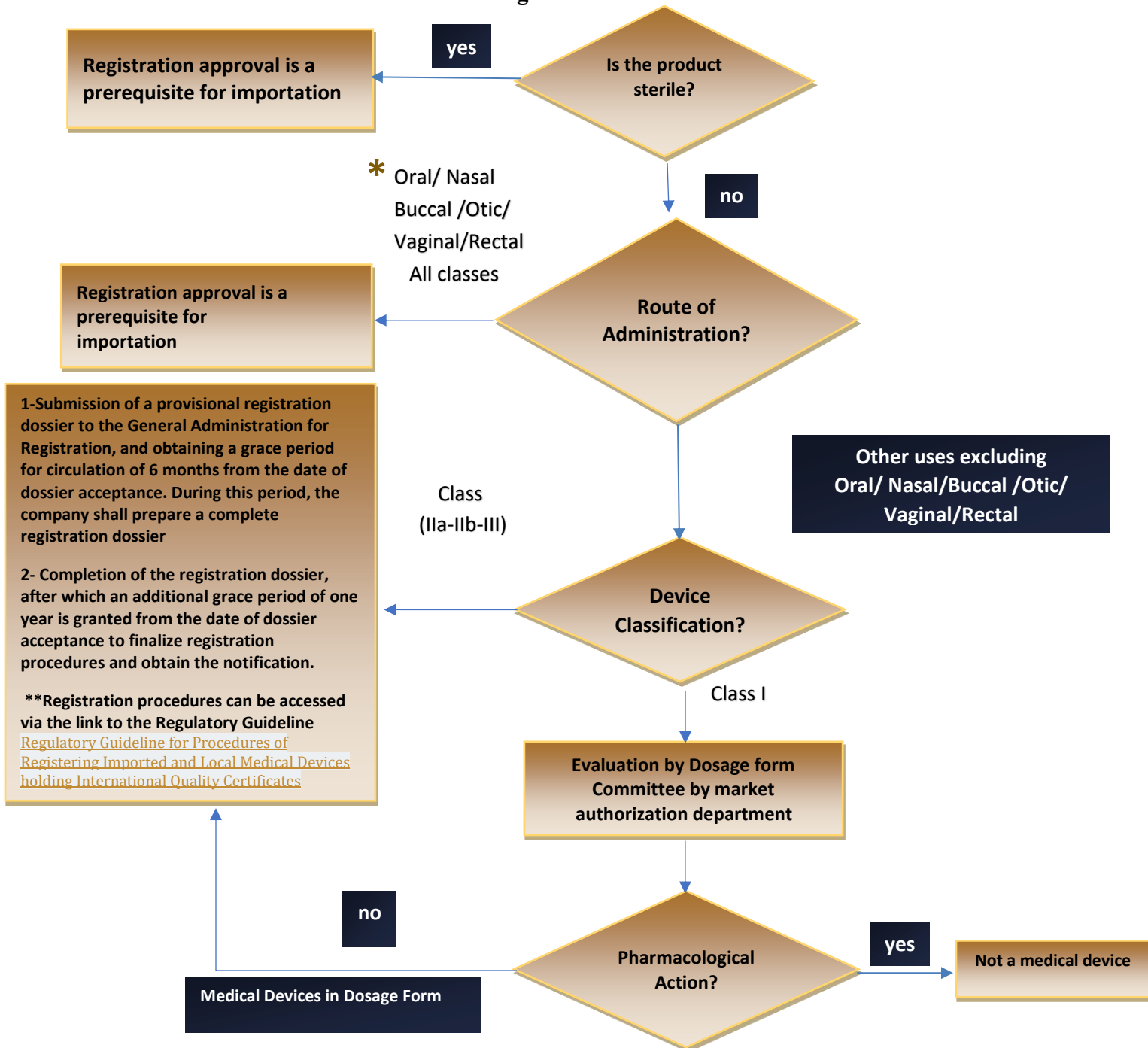


- Completing the registration file; an additional grace period of one year is granted from the date of file acceptance to complete procedures and obtain the notification.

3. Devices classified as (Class I):

- An inquiry shall be submitted to the General Administration for Registration.
- An evaluation is conducted to determine the presence or absence of a pharmacological effect.
 - **If a pharmacological effect is proven:** The product is not considered a medical device and is subject to the Central Administration for Pharmaceutical Products.
 - **If no pharmacological effect exists:** The matter is presented to the Scientific Committee; if approved, the procedure mentioned in Item (2) shall apply.

II. Workflow for Medical Devices in Dosage Form



- In the event that medical devices in the form of vaginal/rectal products obtain a decision from the Scientific Committee of the General Administration of marketing authorization, indicating approval of the product and allowing its marketing, the company shall take the following actions:
- Review the registration procedures via the link to the [Regulatory Guide for the Registration of Imported and Locally Manufactured Medical Devices Holding International Quality Certificates](#) (Clause 4.2).
- Submit a provisional registration dossier before 31/07/2026. A grace period of 6 months for circulation shall be granted from the date of acceptance of the dossier, during which the company shall prepare the complete registration file.
- The registration file shall then be completed, and an additional grace period of one year shall be granted from the date of acceptance of the dossier to finalize the registration procedures and obtain the license.

III. Inquiry Requirements

An inquiry is submitted to the General Administration for Medical Device Registration - Evaluation Department, taking into account the following:

- The application must pertain to one medical device only.
- Applicant data must be clearly included, including an active email and a follow-up phone number.

Required Documents to be Attached:

1. Service fee payment receipt for the medical device inquiry.
2. Registration license in the medical device importers' register (for imported devices) OR the technical operating license (for local factories).
3. Original authorization certified by the Chairman, with bank signature verification for the person responsible for dealing with the Administration.
4. Product sample.
5. Free Sale Certificate (FSC) from a reference country or country of origin, or a CFG from the USFDA (local products exempted).
6. ISO 13485:2016 certificate or a Good Manufacturing Practice (GMP) certificate from the Ministry of Health in the country of origin.
7. Declaration of Conformity.

8. Composition statement specifying active and inactive substances, the role of each substance, and its concentration.
9. Clarification of the packaging form and the final appearance of the package, including raw materials, concentration, activity, and mechanism of action.
10. Inner leaflet (Instructions for Use - IFU).
11. Internal and external labels and artworks.

All documents must be sent in electronic format (Soft Copy) to the Evaluation Department
email: md.sterilereg@edaegypt.gov.eg

Note: To review the registration mechanism for medical devices with a pharmaceutical dosage form (Dosage Form) that have been previously registered / are currently being registered as pharmaceutical products, please refer to the following notice to applicant:

Mechanism for Registration of Medical Devices with Pharmaceutical Dosage Form (Dosage Form)