



MR

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COMPANY

STEP-BY-STEP GUIDE TO SANITARY REGISTRATION WITH COFEPRI S



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STEP-BY-STEP GUIDE TO
SANITARY REGISTRATION
WITH COFEPRIS

INTRODUCCIÓN:

Obtaining sanitary registration with COFEPRIS for medical devices or medications involves several specific steps. The general step-by-step process to obtain this registration is as follows:

1. PREPARATION AND GATHERING OF DOCUMENTATION



Product Identification

- Classification of the medical device or medication.
- Determination of specific requirements according to the classification.



Information Gathering

- Technical Information: Detailed description of the product, technical specifications, manufacturing methods.
- Safety and Efficacy Information: Clinical studies, safety and efficacy tests, biocompatibility, stability tests.
- Administrative Information: Applicant and manufacturer details, certificates, certified translations if necessary.
- Additional Information: Characteristics of the input, packaging material, user manuals, etc.

2. DOSSIER PREPARATION



Document Drafting

- Filling out official forms provided by COFEPRIS.
- Drafting documents or letters according to specific formats and guidelines.
- Translation of documents (if applicable).



Information Review

- Reviewing all documents to ensure completeness and accuracy.
- Correcting any possible errors or inconsistencies.



3. DOSSIER SUBMISSION



Registration Application

- Payment of the corresponding fees.
- Submission of the complete dossier to COFEPRIS, either in physical or electronic format, according to current guidelines.



4. EVALUATION BY COFEPRIS



Technical and Administrative Review

- COFEPRIS conducts a technical and administrative evaluation of the dossier.
- Possible request for additional information or clarifications.



Corrections and Response

- If observations are received, make the necessary corrections and submit the requested additional information.



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5. RESOLUTION



Approval or Rejection

- COFEPRIS issues a resolution on the sanitary registration application.
- If approved, a sanitary registration certificate is issued.



6. POST - APPROVAL



Monitoring and Compliance

- Implement systems for technovigilance, pharmacovigilance, and quality control to monitor the safety and efficacy of the product on the market.
- Maintain compliance with regulations and good manufacturing and distribution practices.



Registration Renewal

- The sanitary registration is valid for 5 years, so it needs to be renewed before expiration. Prepare the required documentation and submit the renewal application on time.

RECOMMENDATIONS

Consult Specific Guide:

- Depending on the type of product, requirements may vary. It is crucial to review the specific guides provided by COFEPRIS for each product category.

Specialized Consulting:

- Consider seeking assistance from a company specialized in the sanitary registration process to ensure compliance with all requirements and avoid errors that could delay approval.

By following these steps and recommendations, the process of obtaining sanitary registration with COFEPRIS can be managed efficiently.



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