



Emergo Group assists medical device companies worldwide with classification, registration, representation and distributor qualification in Mexico as shown below.

COFEPRIS medical device classification

COFEPRIS maintains a large list of medical devices, and each product on this list has a corresponding code that determines its classification (Class I, II or III). Selecting the proper classification code is critical to ensuring a smooth registration process. Our team in Mexico City has many years of experience with medical device classification.

Registration dossier preparation for Mexico

A completed COFEPRIS registration dossier contains similar information found in US FDA and Health Canada submission documents. In fact, COFEPRIS now recognizes US FDA classes I, II and III, PMA or Health Canada Medical Device License approvals as meeting most of Mexico's registration requirements. These devices are also eligible for expedited review by COFEPRIS. If your device already has US or Canadian approval, we will help coordinate the submission to COFEPRIS on your behalf. If your product only has European CE Marking or other national approval, we will leverage information from your existing Technical File or registration dossier to prepare your submission to COFEPRIS. We will also meet with ministry officials to discuss the submission and address follow up questions.

Device labeling and translation

Our office in Mexico City will advise you on device labeling requirements and aid in document translation into Spanish, as required by Mexican law.

Mexico Registration Holder

Foreign companies are required to have a local representative to act as liaison with COFEPRIS. In Mexico, the "Registration Holder" controls the registration of the device. Emergo Group is a licensed, independent Registration Holder with offices in Mexico City. We can act as your Registration Holder in Mexico, allowing you the freedom to select or change distributors at any time in the future without impacting your device registration!

Medical device distributor qualification in Mexico

Mexico has several major markets for medical devices including Mexico City, Monterrey and Guadalajara. Distributors tend to focus on 1-2 of those areas but rarely have coverage throughout the country. We can help find and qualify the best distributors in specific regions of Mexico to maximize your sales nationwide. If we act as your Registration Holder, we will assist in authorizing new distributors on your behalf.

* COFEPRIS is the department within the Secretaria de Salud (Ministry of Health) that oversees medical device registration and vigilance.

** The US FDA does not issue GMP quality system certificates so companies most often request an official Certificate to Foreign Government (CFG) from the FDA to demonstrate their compliance with FDA regulations. European Competent Authorities issue a similar document called a Certificate of Free Sale (CFS). Many Class I device manufacturers, which do not need to comply with US or European QMS requirements, are accommodated by COFEPRIS.

*** Manufacturers must have proof of FDA inspection available.

^^ Devices with US FDA 510(k) clearance, PMA approval or are approved Medical Device License (MDL) from Health Canada will meet the COFEPRIS registration dossier requirements.

^^ Foreign clinical data and testing done to international standards will most often be accepted by COFEPRIS.