



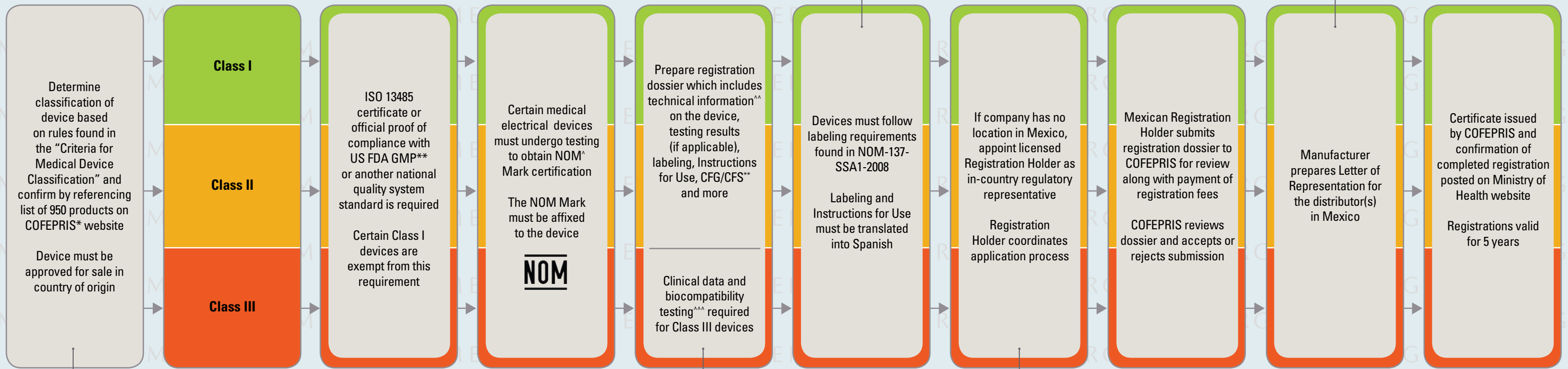
Emergo Group has been assisting medical device and IVD companies with international regulatory issues and quality management system compliance since 1997. Whether you are entering the Mexican market for the first time or introducing another new device, we can assist with every step of the process from device classification and COFEPRIS registration to distributor selection. With offices in Mexico and worldwide, Emergo Group can help you obtain regulatory clearance, maintain compliance and increase sales in the world's largest and fastest growing medical device markets.

Guidance on 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.

Finding qualified distributors throughout 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 Mexico. We can help find and qualify the best distributors in specific regions of Mexico to maximize your sales in the country. If we act as your Registration Holder, we will assist in authorizing new distributors on your behalf.



Proper COFEPRIS* device classification is critical

The COFEPRIS system of classifying medical devices can be confusing. 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.

Preparing your registration dossier

A completed COFEPRIS registration dossier contains similar information found in US FDA and CE Marking submission documents. We will take information found in one of these documents (if available) to prepare your dossier in the proper format accepted by COFEPRIS.

Mexican Registration Holder representation

In Mexico, the Registration Holder controls the registration of the device. Emergo Mexico s.r.l. 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!

* 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).
 ^ NOM is an acronym for "Normas Oficiales Mexicanas." With the exception of NOM testing for electrically powered products, product testing performed to international standards will be accepted.
 ^^ Although a FDA 510(k) or EU Technical File is not accepted by COFEPRIS, the information contained in these documents will satisfy the requirements needed for the submission with the exception of NOM testing.
 ^^ Foreign clinical data and testing done to international standards will most often be accepted by COFEPRIS.