



Emergo Group assists medical device companies worldwide with classification, registration, and representation in South Korea as shown below.

KFDA device classification

Medical devices in South Korea are classified according to Notification 2000-37 published by the Korean Food and Drug Administration (KFDA). Our team in Seoul is extremely well-versed in device classification and will ensure that your device is properly classified, the first step toward ensuring a smooth registration with KFDA.

Korea KFDA technical file preparation

Despite the name, a KFDA Technical File is more like a US FDA 510(k) or PMA than a European Technical File or Design Dossier. Foreign manufacturers without a local office in South Korea cannot submit these technical files directly to the KFDA as this must be done through the Third Party License Holder. We will help prepare the appropriate Technical File for your device, interact with KFDA and assist in having all necessary documents translated into Korean, as required by law.

Securing product licenses

Once your Class II, III or IV technical file has been approved by the KFDA, proof of registration and compliance with testing requirements must be submitted to obtain a product license. We will help coordinate the submission of your approvals or, in the case of Class I devices, submit the proper notification documentation to KFDA.

Third Party License Holder representation in Korea

Companies that do not have a physical presence in Korea must appoint a local representative called a "Third-Party License Holder." Having an independent firm, rather than a distributor, control the registration for your device is critical to maintaining control over registration and distribution of your product. Emergo Group can assist you in with Third Party License Holder representation.

KGIP – Korea Good Import Practice

Similar to Korea Good Manufacturing Practices (KGMP) certification for Korean manufacturers, KGIP is intended as a way for the KFDA to control products placed in the market by foreign manufacturers, and includes control over product release, post market surveillance and vigilance activities. The KGIP is undertaken and held by your Third Party License Holder (TPLH). The KFDA accepts ISO 13485 or ISO 9001 (Class I only) certificates as proof of manufacturer's QMS compliance in conjunction with the TPLH's KGIP. Acting as your THLP, we can fully assist in obtaining KGIP certification.

Finding medical distribution partners in Korea

Foreign manufacturers find screening potential distribution partners in South Korea to be extremely challenging. Like many countries in Asia, South Korea has a complicated culture that can be difficult for a "foreigner" to understand. To work through those issues, our Seoul-based consulting team can evaluate potential partners, making sure you select reputable companies who will maximize sales and uphold your reputation in South Korea.

* Foreign manufacturers cannot submit applications to the KFDA directly unless they have a local office in South Korea who will also act as the Third Party License Holder.

** The Safety and Effectiveness Review (SER) Technical File is required for medical devices with innovative features such as new materials, unique modes of action, technology, or effectiveness.

^ The General Technical File is comparable to a US FDA 510(k) submission. The SER Technical File is more like a US FDA PMA submission.

^^ Local clinical trials are typically not required. Foreign clinical data may be acceptable after being validated. Generally, the KFDA will accept clinical data that has been approved by another foreign government or published in a SCI-listed scientific journal. CE Marking certificates are accepted for products manufactured in Europe, but not, for example, from US companies with a CE certificate.

^^^ The Korea Testing Lab (KTL) is authorized to conduct testing on all categories of medical devices. Several other labs can also conduct testing, but not on all categories of devices. Existing testing must have been completed in accordance with ISO, IEC, ASTM or GLP standards. Performance testing from labs certified to ISO/IEC 17025 are accepted.