

FAQ: re medical device manufacturing and trading in China.

Q. What are the licensing requirements for a medical devices (manufacturing and export) WFOE enterprise for Class 1 non sterile devices? (Class 1 non sterile device which is exempt from listing with the Ministry of Health).

A. A manufacturing WFOE is required with a trading business scope. The approval authorities will require the WFOE to be registered in order to obtain the necessary production and environmental licenses. This is because to obtain the business license there has to be an inspection of the manufacturing premises by the environmental department to obtain this license before the business license is issued and ancillary licenses. Also the medical device product permit registration has to be applied for where the device is manufactured. The WFOE would obtain the environmental license, production license and the branch, the sales operation license.

Q. They also have a distributor here already in China who they believe has the necessary licenses in place but they are looking to also trade other products as well and possibly do training on these products as well.

A. If they are intending to include a range of products then they need to properly identify all the products with reference to the relevant HS tariff codes. Training on the products should be able to be included as ancillary activities under the business license.

Q. Do you also know whether it is possible for a company set-up in one province and whether this could be done with a branch office for the factory in other province?

A. If the WFOE is intended to have a manufacturing and trading scope it can be established in one province and then a branch office license applied for in the other province. The branch office license cannot be applied for until the WFOE business license is obtained.

Q. Are there any advantages to setting up a branch office over setting up two unrelated WFOEs (ie doesn't both the parent and branch office have to report separately to their respective local tax and other authorities)?

A. Two separate WFOEs require higher capital investment.

As a branch it will have to separately report fapiaos to its relevant tax authority and its turnover tax to the SAT where the WFOE is registered however the WFOE should be able to file consolidated annual accounts.

Q. If possible can you please give some indication as to a potential quote for WFOE and any additional indicative costs for other services (business license; medical license; environmental licenses,)?

A. The investor will need to notarise and/or legalise certain corporate documents for submission to the approval authorities. Before a detailed quote can be given it must be determined where the Investor is domiciled. If it is considering entering using a HK corporate vehicle, the incorporation and notarisation costs will be about USD4000.

Onshore the legal costs for establishing the WFOE would be between USD25000-30000. This depends on whether this is a Greenfield site or manufacturing premises will be leased. Also the State Drug and Food Administration (Medical Device Production) Regulations will have to be complied with. After the business license is issued the medical device has to be submitted for "product permit registration" with the SDFA. If the medical device is being manufactured here, it will be classed as a domestic medical device and if it a Class 1 then the registration approval should be obtainable at provincial level registration whether Class 1 or not.

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