

B. China Agent

Introduction

Any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device imported into the China must identify a China agent for that establishment. Each foreign establishment may designate only one China agent. The foreign establishment may also, but is not required to, designate its China agent as its official correspondent. The foreign establishment should provide the name, address, telephone and fax numbers, and e-mail address of the China agent.

Responsibilities of a China Agent

The China agent must either reside in the China or maintain a place of business in the China. The China agent cannot use a post office box as an address. The China agent cannot use just an answering service. They must be available to answer the phone or have an employee available to answer the phone during normal business hours.

The responsibilities of the China agent are limited and include:

- Fully responsible for the record or registration of the imported medical device.
- Fully responsible for the manufacturing/distributing license of the imported medical device.
- Assist CFDA in communication with the foreign establishment.
- Respond to questions concerning the foreign establishment's devices that are imported or offered for import into the China.
- Deliver the relevant regulations and product standards accurately (technical requirement) to the foreign establishment.
- Gather the adverse events after the product is released to the market and give feedback to foreign establishment, report to the corresponding food and drug supervision and administration department simultaneously.



- Coordinate with the recalls after the product is released to the market and report to the CFDA simultaneously.
- Other responsibilities involved with product quality and after-sale service.
- If CFDA is unable to contact the foreign establishment directly or expeditiously, CFDA may provide information or documents to the China agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.