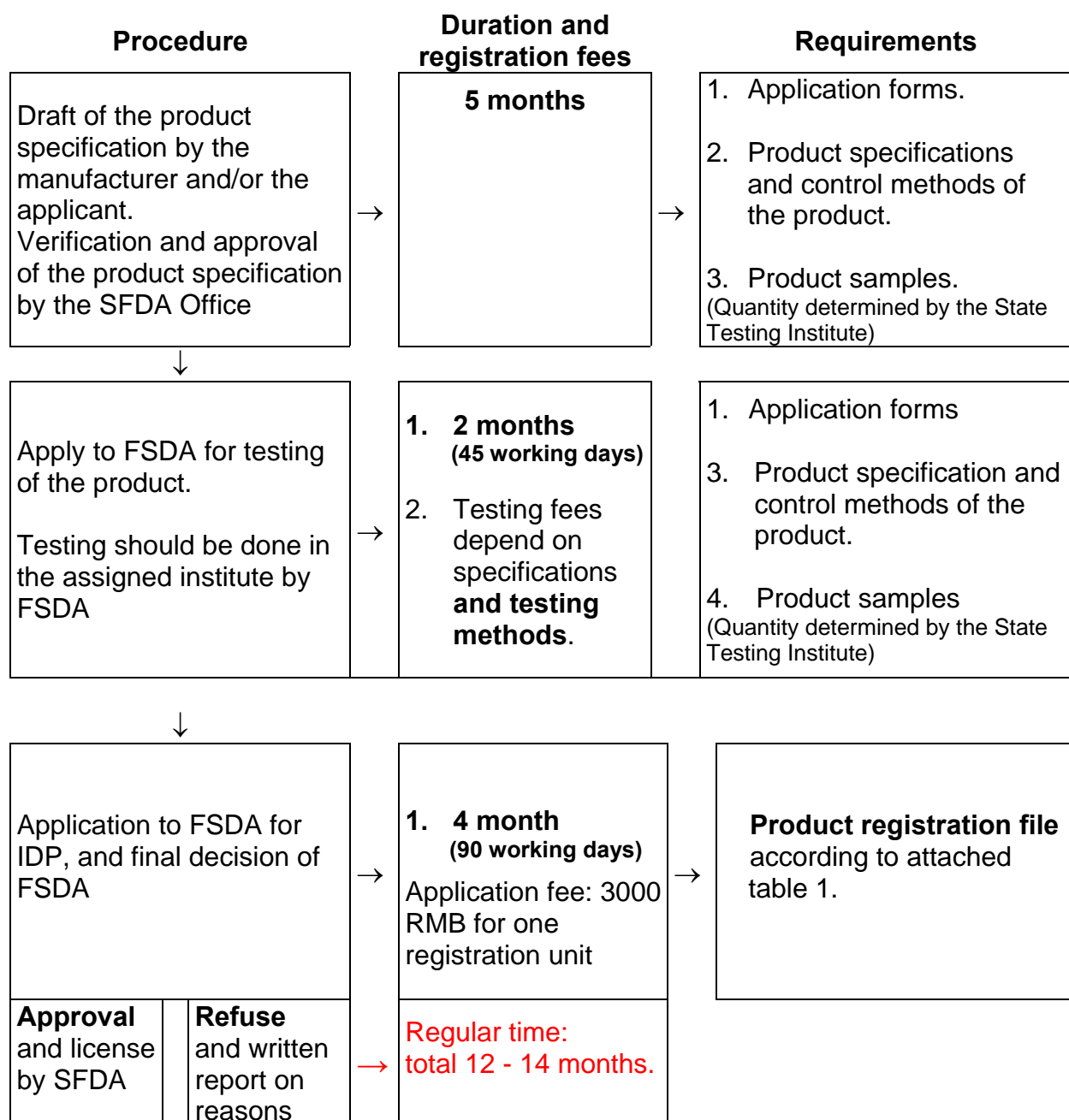


## Import Medical Device Registration Procedure

According to the regulations of the State Food and Drug Administration (SFDA), all medical devices are classified into 3 classes. Those 3 classes are ranged from 1 to 3 with view to the potential risks considering the intended use. Of importance for classification is the duration of use on or in the human body and if the device is categorized as an active medical device (operated with an external power source) or non active medical device. For registration of medical devices class 2 and 3, SFDA expects for having implemented a strict quality control and documentation system.

### Registration Procedure for Import Medical Devices Class II and III



**Table 1: List of documents for application of Import Medical Device Registration for class II and III products**

No	Documents
1	Manufacturer's certificates for the legal qualification of production of the medical device
2	Document certifying the qualification of the applicant
	Letter of Entrustment from the manufacturer to the applicant if it entrusts the applicant as agent to register the product
3	Free Sales Certificate of the product in the manufacturer's country issued by the Medical Device Administration Authority of this country
4	Quality standards of the product: safety requirements and technical characteristics and specifications etc. and their testing methods
5	Product Operation Manual and photo of the product
6	Clinical trial report of the product
7	Test and examination report of the product issued within one year by the Quality Control Institute designed by SFDA (in China)
8	Conformity Declaration (specified to the applied products and assuring that the quality of the product that will be registered and sold in China is conform to the quality of the product sold in the producing country )
9	Letter of Entrustment from the manufacturer to the sales agent in China for after sales service of the product and the agent's consent letter with its commercial license
10	Self-declaration of the manufacturer assuring that all the documents for registration application are true and correct

Note:

1. The documentation should be submitted as original version, signed or sealed by the manufacturer.
2. The items 1, 2, and 3 can be submitted as copy, but notarisation is needed.
3. All documents must be translated into Chinese language.
4. Devices of class III must be tested in a clinical trial, at least in 2 hospitals proposed by SFDA, if it is their first time to be registered in China, and the manufacturer will have an inspection in site on his QC/QM -system by officers sent by SFDA if it is the first time to register his product manufacturing for class III devices.
5. For devices of the class I, the product samples and the test report is not required as well as a clinical trial in China.