



Accepted No: \_\_\_\_\_

# State Food and Drug administration

## Application Form of Clinical Trail Approval for Medical Device

**Product Name:** \_\_\_\_\_

**Applicant:** \_\_\_\_\_

**Agent:** \_\_\_\_\_

### State Food and Drug administration

NOTE: Please read the form filling explanation

Testing Medical Device Name	Chinese			
	Original			
	English			
Structure Feature	Active <input type="checkbox"/> Passive <input type="checkbox"/>			
Model and Specification				
Structure and Constitution				
Application range				
Applicant	Name	Chinese		
		Original		
		English		
	Address	Chinese		
		Original		
		English		
	Linkman		Tel.	
	Fax.		Email	
	Postcode		Organization Code	
Application Location				



Manufacturer Address	Chinese			
	Original			
	English			
Agent	Name			
	Address			
	Postcode			
	Linkman		Tel.	
	Fax.		Email	
	Agent Location		Organization Code	
<b>Attached Data</b>				
1.Copy of Duplicate of Business License (Domestic Application)		<input type="checkbox"/>		
2.Copy of Organization Code License (Domestic Application)		<input type="checkbox"/>		
3.Proof documents about product can be sold in market issued state ((region) competent departments of medical device on applicant domicile or manufacture location.		<input type="checkbox"/>		
4.Power of attorney of Oversea Applicant appoint agent in china		<input type="checkbox"/>		
5.Agent commitments		<input type="checkbox"/>		
6.Copy of Duplicate of Business License or Organization Registration Certificate of agent		<input type="checkbox"/>		
7.Testing product description		<input type="checkbox"/>		
8.Preclinical study data		<input type="checkbox"/>		
9.Product technical requirements		<input type="checkbox"/>		
10.Product registration inspection report and pre-assessment feedback form		<input type="checkbox"/>		
11.Product instruction and label sample		<input type="checkbox"/>		
12.Clinical trials protocol		<input type="checkbox"/>		
13.Written comments of clinical trials approval wrote by Ethics Committee		<input type="checkbox"/>		
14.Declaration of Conformity		<input type="checkbox"/>		
15.Notarized copy about Original/ English documents issued by notary organization on applicant location.		<input type="checkbox"/>		
<b>Other problems need to be explain</b>				
Applicant/Agent(Signature and Seal)		Preparer(Signature)		
Date:	Year    Month    Day	Date:	Year    Month    Day	