Item	Filing Guide for Manufacturing of Class-I Medical Devices in Zhengzhou District of China (Henan) Pilot Free Trade Zone
No. of Corresponding Responsibility	
Issuer	Zhengzhou Food and Drug Administration
Applicant	Legal Person
Basis for Implementation	
Application Requirements	Those engaged in medical devices production shall meet the following requirements: 1. Having production sites, environmental conditions, production equipment and professional and technical personnel in accordance with medical equipment production; 2. Having institutions or full-time inspection personnel and equipment to conduct quality inspection on medical equipment production; 3. Having management system that ensures the quality of medical equipment; 4. Having after-sales service capability in accordance with medical equipment production; 5. Being accordance with the requirements specified by product development, production process documents.
Application Materials	I. Description of change and related documentary evidences; when the entrusted party applies for filing of information of the commissioned product or filing change of production of Class-I medical equipment, in addition to materials required by *Regulations for the Supervision and Administration of Medical Devices*, the following shall be submitted too: 1. Copies of the entrusting party's and the entrusted party's business license and Organization Code Certificate;

	2. Copy of the entrusted party’s medical equipment production license or filing certificate of Class-I medical equipment production; 3. Copy of the entrusting party's filing certificate of commissioned production of medical equipment; 4. Copy of the commissioned production contract; 5. Specification and label sample to be used for commissioned medical equipment; 6. Approval of the entrusting party to the quality management system of the entrusted party; 7. Self-guarantee statement of the entrusting party for the commissioned medical equipment’s quality, sales and after-sales service responsibility. For the commissioned production of equipment which does not fall into the category of domestic medical equipment approved in accordance with special innovative medical equipment approval procedures, copy of the entrusting party’s medical equipment production license or filing certificate of Class-I medical equipment production shall be submitted; for the commissioned production of equipment which falls into the category of domestic medical equipment approved in accordance with special innovative medical equipment approval procedures, evidence of special approval for innovative medical equipment shall be submitted. II. Certificates of approval; III. Declaration of conformity.
Procedures	Acceptance→ Tech Examination→ On-site Inspection→ Review→ Conclusion
Duration	3 workdays
Implementation Authority	Zhengzhou Food and Drug Administration
Charges	No
Standard Fees	N/A
Basis for Charges	

Online Application Available	No
Supervisor	
Working Hours	9：00—12:00; 13:00—17:00
Office Location	Building No.1, Oriental International Plaza, No. 85, Jinshui East Road, Zhengzhou City (Postal code: 450046)
Tel.	
Complaint Hotline	
Application Forms	
Flow Chart	
FAQ	
Remarks	