

Item	First Class Medical Device and Product Filing Guide of Zhengzhou Comprehensive Service Center of China (Henan) Pilot Free Trade Zone
Number of Corresponding Responsibility	
Issuer	Zhengzhou food and drug administration.
Applicant	Legal person
Implementation Principles	
Application Requirements	
Application Materials	<p>(I) Submits: 1. register of Class I medical equipment which is printed online and affixed with seal (automatically generated, printable); 2. Safety risk analysis report; 3. requirements for product technology; 4. product inspection report; 5, clinical evaluation data; 6. product specifications and tag design sample of the smallest sales unit; 7. manufacturing information; 8. certification documents; 9. declaration of conformity; 10. Power of Attorney of legal representative. The documents to be filed shall be complete and clear, which shall be bound in A4 paper with a table of contents attached. These documents shall be submitted together with the electronic version after the affixation of official seal. (II) Requirements for the declaration documents: 1. the declaration documents shall be provided with an index, each part shall have a cover sheet, and documents shall be divided by a separating page. 2. The declaration documents shall be bound into a book according to the index. 3. The declaration documents shall be made in one copy, which shall be printed clearly and completely on A4 paper, without alteration. Documents issued by the government departments and other agencies shall be provided in the original size. Any bound book must not be separated without permission. 4. If declaration documents are copies, they must be clear and consi</p>

	<p>stent with the original. 5. The application contents in all documents should be consistent. 6. The declaration documents shall be stamped with the official seal.</p>
Procedures	Acceptance → technical review → on-site inspection → audit → conclusion → announcement
Duration	3 workdays
Implementation Authority	Zhengzhou food and drug administration.
Charge or not	None
Standard Fees	None
Basis for Charges	
Online Application Available	None
Supervisor	
Working Hours	9:00-12:00 AM; 1:00-5:00 PM
Office Location	Building No. 1, Orient International Plaza, Yabao, No. 85, Jinshui East Road, Zhengzhou (Post code: 450046)
Tel.	
Complaint Hotline	
Application Forms	

Flow Chart	
FAQ	
Remarks	