CFDA registration documents checklist

Primary title	Secondary title
Document 1: Application Form	
Document 2: Letter of Authorization for Agent	
Document 3: List of Basic Requirements for Safety and Effectiveness of Medical Device	
Document 4: Overview	Document 4.1 Executive Summary Document 4.2 Device Description Document 4.3 Catalogue/Model Document 4.4 Package Description Document 4.5 Indication and/or Intended Use and Contraindications Document 4.6 Reference to Similar and Previous Generations of the Device (if have) Document 4.7 Other description
Document 5 Research Documents	Document 5.1 Performance Study Document 5.2 Biocompatibility Evaluation Study Document 5.3 Biological Safety Study Document 5.4 Sterilization and Disinfection Process Study Document 5.5 Shelf Life and Package Study Document 5.6 Animal Study Document 5.7 Software Study Document 5.8 Other Study
Document 6 Manufacturing Information	Document 6.1 Manufacturing Processes Document 6.2 Design and Manufacturing Sites
Document 7 Clinical Evaluation	
Document 8 Risk Analysis	
Document 9 Product Specifications	
Document 10 Registration Test Report	Document 10.1 Test Report Document 10.2 Pre-evaluation Comments
Document 11 Instructions for Use and Label	Document 11.1 Instructions for Use Document 11.2 Label of smallest trading unit
Document 12 Conformity Statement	