Appoint a China-based agent if based outside China.

Class: I, IIa, IIb, III

Determine medical device class according to National Medical Products Administration (NMPA) Medical Device Classification Catalog.

Class I: Low-risk medical devices whose safety and effectiveness are ensured through routine administration

OR

Class II: Mid-risk medical devices that require further control in order to ensure their safety and effectiveness

OR

Class III: Imported and high-risk medical devices that must be strictly controlled in respect to safety and effectiveness, including all products that incorporate artificial intelligence (AI)

Prepare registration dossier for unexempted Class II devices and Clinical Evaluation Report in accordance with all regulations.

Prepare registration dossier for Class III devices and Clinical Evaluation Report in accordance with all regulations.

Provincial level:
Submit medical device filing to NMPA.

DHT Class: I

Clinical investigation is not required.

Provincial level:
NMPA standard medical device registration certificate

DHT Class: II

Clinical investigation may be required if a ***clinical evidence evaluation*** is not sufficient.

Provincial level:
NMPA Innovation Green Pathway medical device registration certificate

DHT Class: II

Clinical investigation may be required if a ***clinical evidence evaluation*** is not sufficient.

National level:
NMPA standard medical device registration certificate

DHT Class: III

Clinical investigation is required.

National level:
NMPA Innovation Green Pathway medical device registration certificate

DHT Class: III

Clinical investigation is required.

Product assessment (aside from regulatory review), pricing, reimbursement, and patient access are primarily accomplished by **local** purchasers on a case-by-case basis (i.e., provinces, healthcare providers, health systems).

NO national Health Technology Assessment (HTA) process for DHTs

NO national pricing or reimbursement processes for DHTs

NO national patient access pathways for DHTs

Key

Step that applies to a **national** process

Step that applies to a **local** or **regional** level

Details regarding clinical data:

Clinical evidence evaluation *refers to the review of published data.*

Clinical investigation *refers to a systematic investigation or study undertaken to verify the safety and performance of a device.*

NO **national** pathways for DHTs