

CHINA Regulatory

Category Name	Medical Device	
Responsible Regulatory Agency	National Medical Products Association (NMPA)	
Product Risk Classifications	Class II	Class III
Regulatory Review	Class II products are not reviewed by NMPA, but qualify for review at the provincial level, where different requirements may apply.	Class III products qualify for review by NMPA.
Pre-Submission Opportunities	Not mandatory, but recommended	
Guidelines To Be Met	<p>No set standards for DTx products at this time; guidelines are determined on a case-by-case basis.</p> <p>Class II products are evaluated based on their intended purpose and risk. They typically have a limited impact on clinical behavior changes.</p> <ul style="list-style-type: none"> • Registration required • Clinical evaluation required (smaller study sample sizes generally accepted) • Randomized Control Trial (RCT) may be required • Technical Review Guideline for Mobile Medical Devices and Mobile Devices • Cybersecurity requirements 	<p>No set standard for DTx products at this time; guidelines are determined on a case-by-case basis.</p> <p>Class III products are evaluated based on their intended purpose and risk. They typically have a higher risk profile and greater impact on clinical behavior changes.</p> <ul style="list-style-type: none"> • Registration required • Clinical evaluation required (larger study sample sizes generally required) • Randomized Control Trial (RCT) is required • Technical Review Guideline for Mobile Medical Devices and Mobile Devices • Cybersecurity requirements <p>Guideline requirements:</p> <ol style="list-style-type: none"> ISO13485:2016 Medical devices—Quality management systems GB/T 25000.51-2016 Systems and software Quality Requirements and Evaluation (SQuaRE)—Part 51: Requirements for quality of Ready to Use Software Product (RUSP) and instructions for testing YY/T 0316-2016 Medical devices—Application of risk management to medical devices YY/T 0664-2020 Medical device software—Software life cycle processes <p>https://www.cmde.org.cn/CL0019/22680.html</p>
Product Recognition	Licensed	
Approximate Timing For Process Completion	6 months for review	

CHINA Reimbursement

Public Insurance Coverage	Basic Medical Insurance (BMI) does not cover DTx products at this time.
Private Insurance Coverage	Private insurance coverage is not common in China. Existing plans do not cover DTx products yet.
Employer-Sponsored Healthcare	Critical illness insurance may cover DTx products in the future for condition-specific products (i.e., cancer).
Consumer-Funded	Most patients are not willing to pay for DTx products due to the presence of universal health insurance.

Note: This document represents pathways that continue to evolve. It does not provide legal advice.