## Category Name
Medical Device

### Responsible Regulatory Agency
National Medical Products Association (NMPA)

### Product Risk Classifications

<table>
<thead>
<tr>
<th>Class II</th>
<th>Class III</th>
</tr>
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<tbody>
<tr>
<td>Class II products are not reviewed by NMPA, but qualify for review at the provincial level, where different requirements may apply.</td>
<td>Class III products qualify for review by NMPA.</td>
</tr>
</tbody>
</table>

### Regulatory Review

#### Class II
- Class II products are not reviewed by NMPA, but qualify for review at the provincial level, where different requirements may apply.

#### Class III
- Class III products qualify for review by NMPA.

### Pre-Submission Opportunities

Not mandatory, but recommended

### Guidelines To Be Met

#### Class II
- No set standards for DTx products at this time; guidelines are determined on a case-by-case basis.
- Class II products are evaluated based on their intended purpose and risk. They typically have a limited impact on clinical behavior changes.
  - 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

#### Class III
- No set standard for DTx products at this time; guidelines are determined on a case-by-case basis.
- 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.
  - 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

Guideline requirements:
- a) ISO 13485:2016 Medical devices—Quality management systems
- b) 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
- c) YY/T 0316-2016 Medical devices—Application of risk management to medical devices
- d) YY/T 0664-2020 Medical device software—Software life cycle processes

[https://www.cmde.org.cn/CL0019/22680.html](https://www.cmde.org.cn/CL0019/22680.html)

### Product Recognition
Licensed

### Approximate Timing For Process Completion
6 months for review

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## 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.

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