Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Progress of Medical Device Regulation in China

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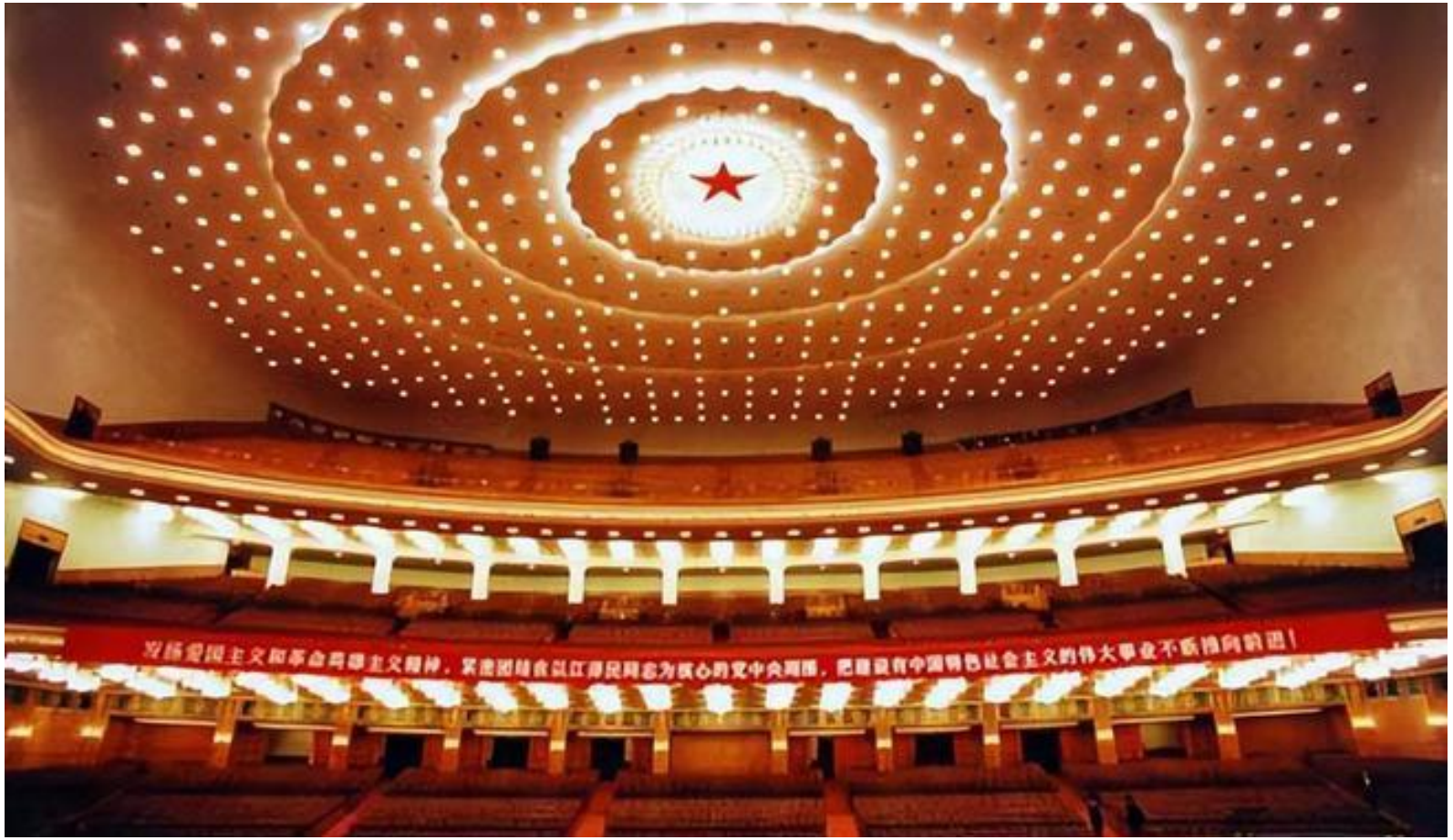
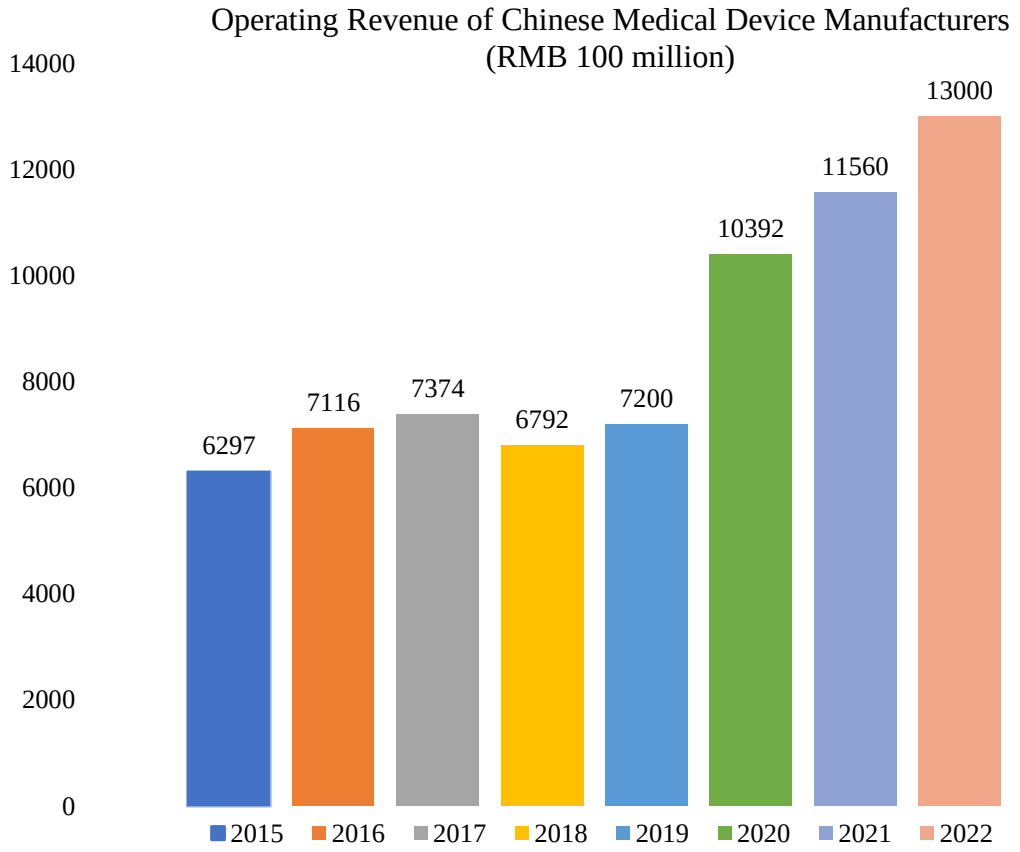


Paramountcy of Life
Put People First

Development of the Medical Device Industry

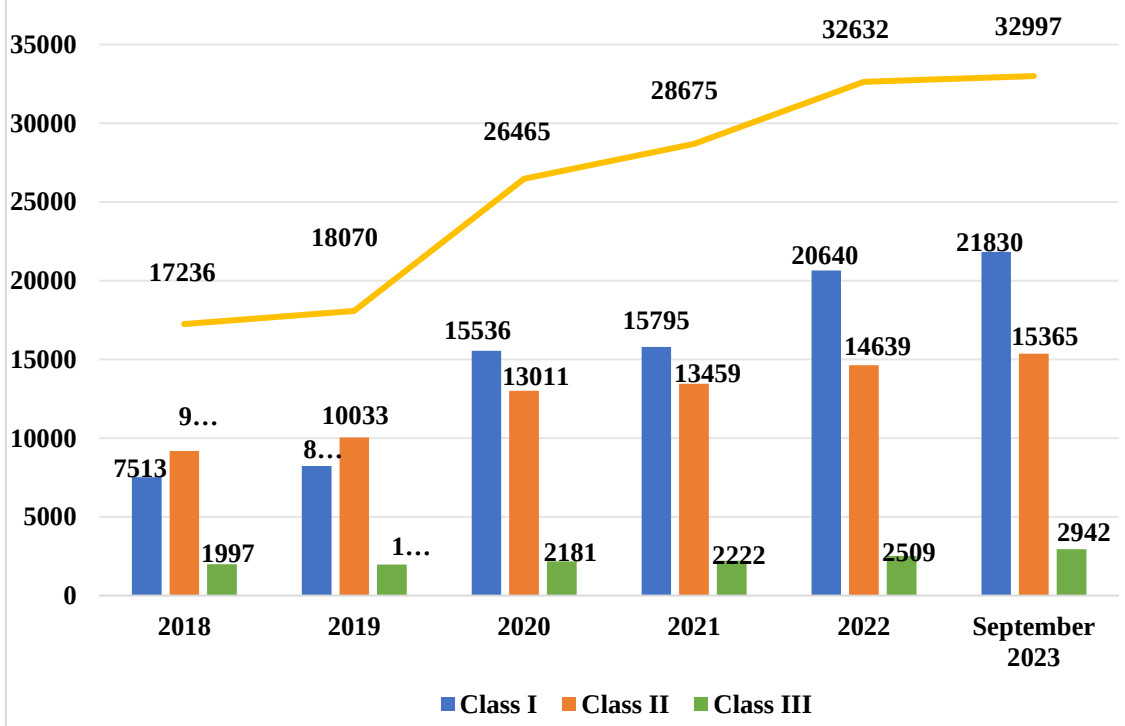
China’s Medical Device Industry Scale

- **In recent years, the operating revenue of Chinese medical device manufacturers has increased steadily.**
- **In 2022, the operating revenue of China’s medical device industry reached RMB 1.3 trillion, with a growth rate of about 12%.**

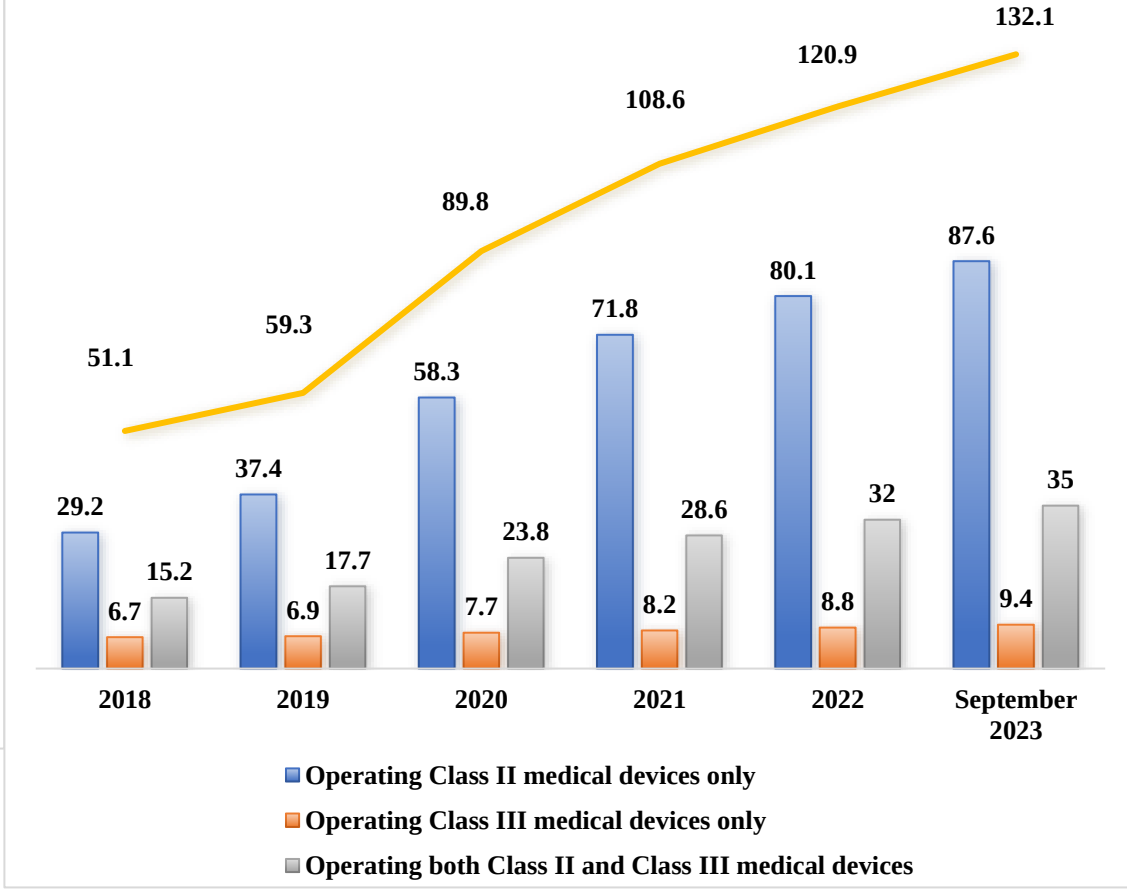


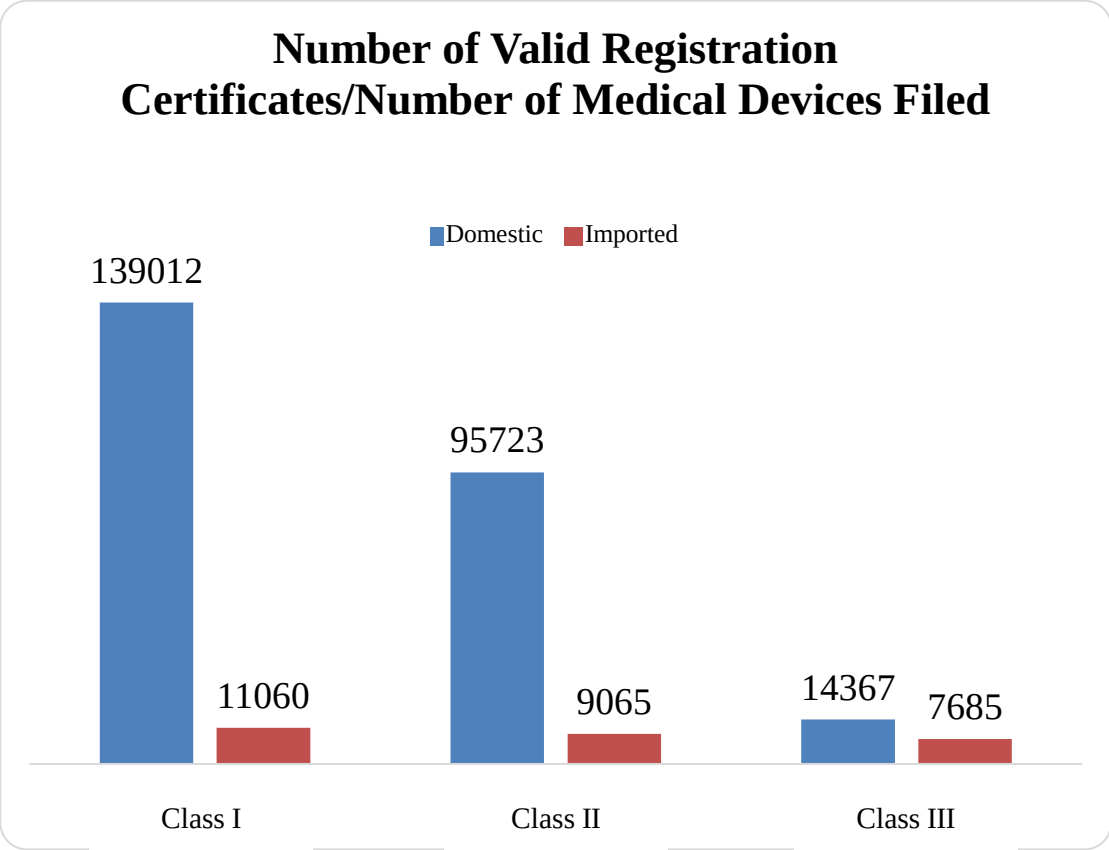
Note: Data from the National Medical Products Administration Institute of Medical Economics

Number of Medical Device Manufacturers (Unit: 1)



Number of Medical Device Distributors (Unit: 10,000)





At present, a total of 126,840 registration certificates have been issued for Class II and Class III medical devices.

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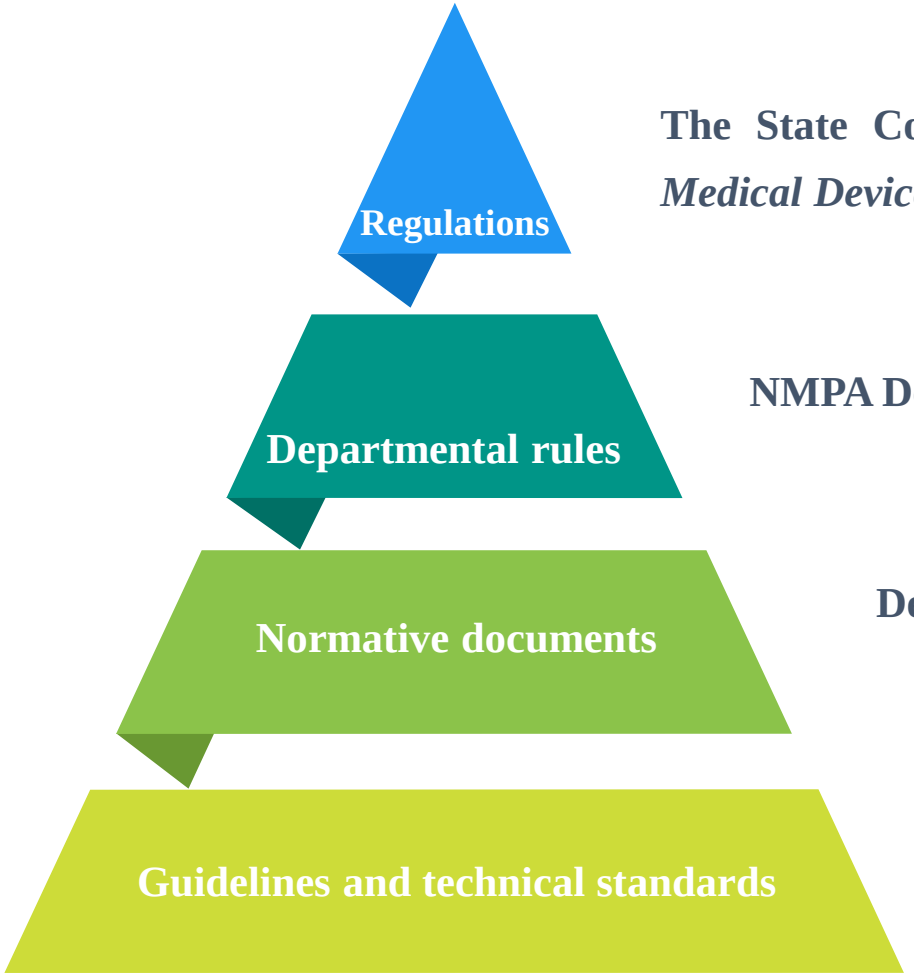
Progress and Achievement of Medical Device Regulation

1. The new medical device regulatory system has basically taken shape



The State Council - *Regulations for the Supervision and Administration of Medical Devices* (Decree No.739)

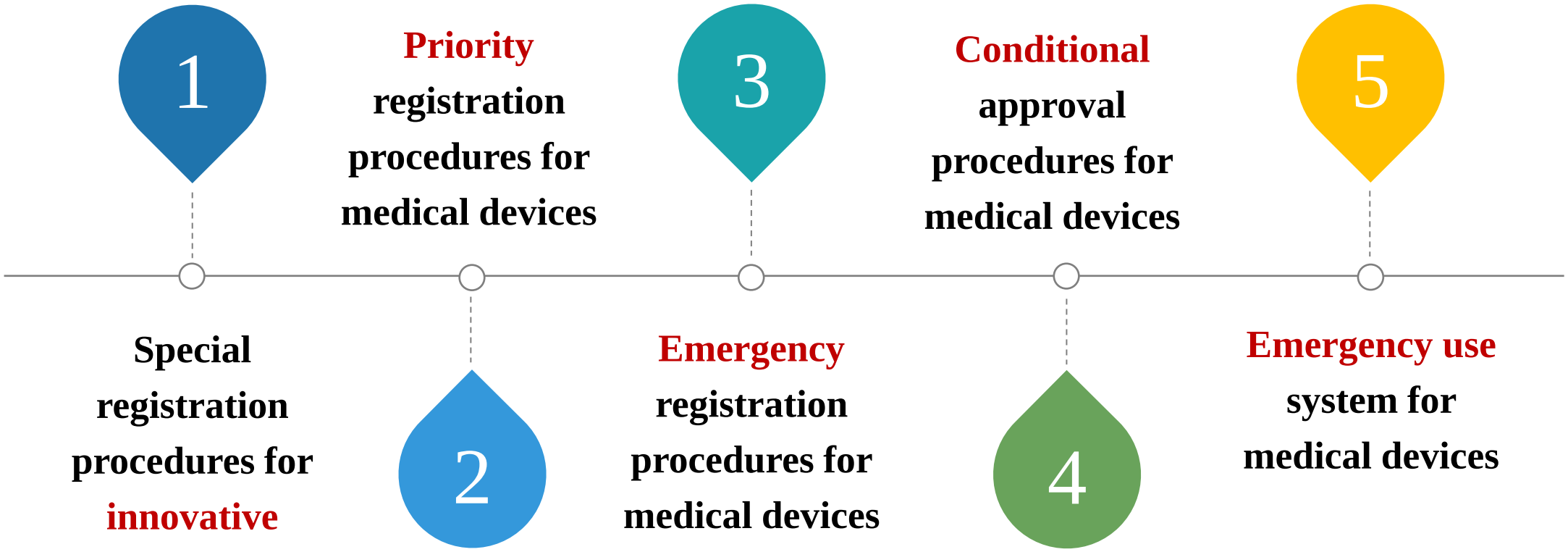
NMPA Decree - 14 provisions

Departmental specifications - More than 130

Nearly 600 guidelines for technical review

1,964 standards

2. The innovation and development of the medical device industry have been continuously encouraged



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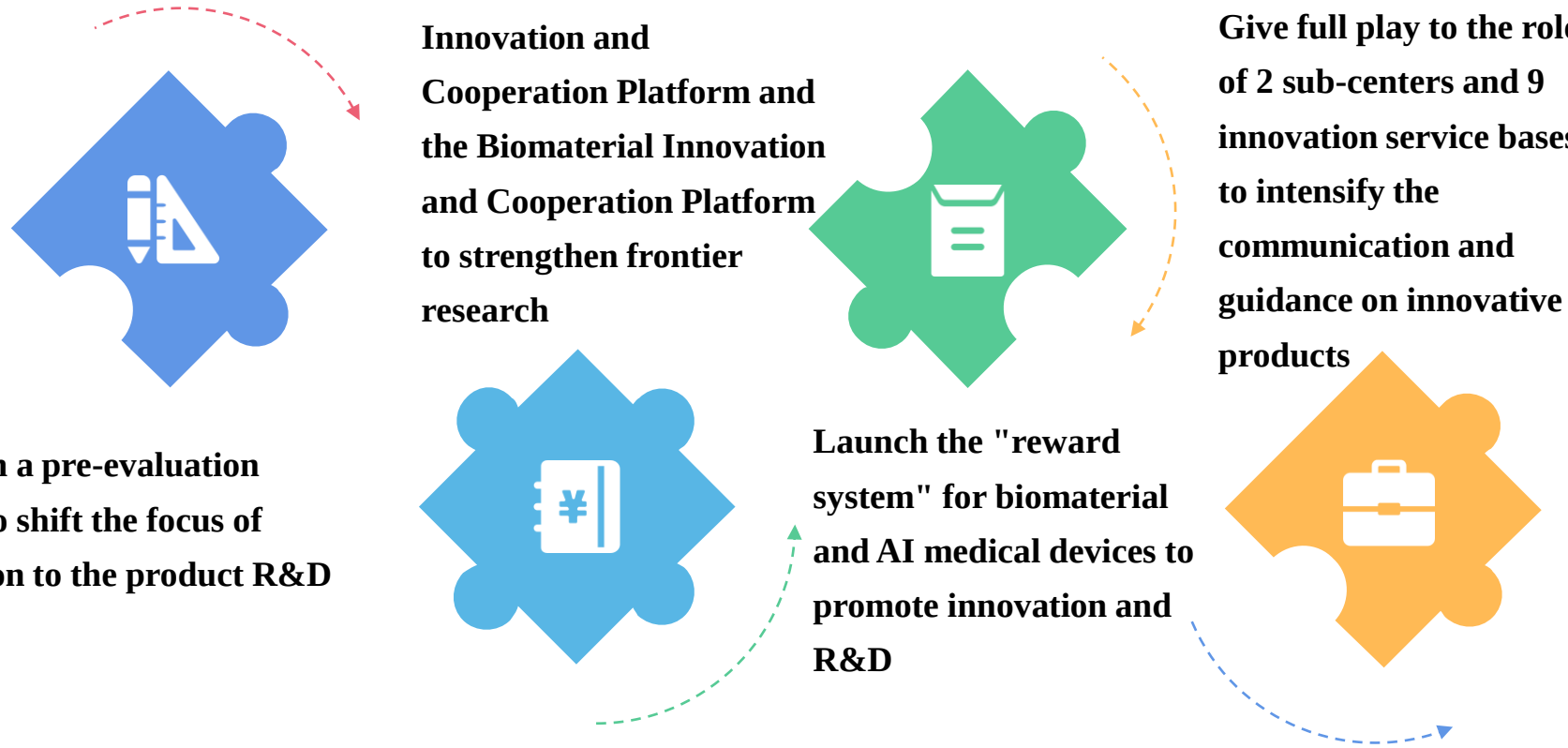

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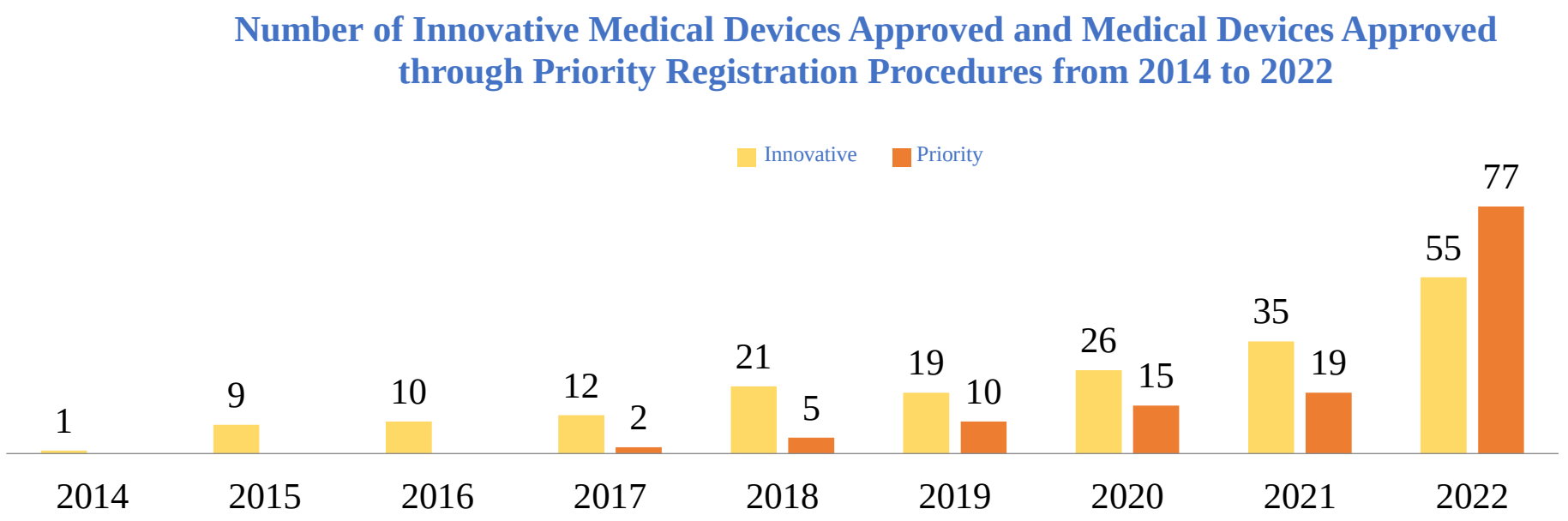
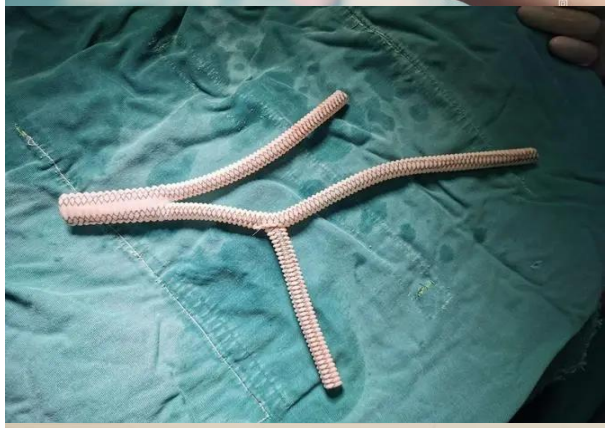




NMPA has approved 238 innovative medical devices for marketing and 137 medical devices through the priority registration procedures.

3. The medical device regulation in the whole life cycle has been continuously strengthened

Tier	Responsibilities			
NMPA	Responsible for the supervision and management of medical devices nationwide	Organize and conduct an overseas inspection of imported medical devices	Guide and supervise the regulation related to production, sales, and use of medical devices nationwide	
Provincial Medical Products Administrations	Responsible for the review and approval of Production Permits for Class II and Class III medical devices within their respective jurisdictions	Responsible for the routine supervision and management of medical device manufacturers within their respective jurisdictions	Guide and supervise the regulation related to the sales and use of medical devices within their respective jurisdictions	
Municipal Regulatory Authorities with Districts	Responsible for the filing of Class I medical device manufacturers within their respective jurisdictions	Responsible for the review and approval of Sales Permits for Class III medical devices and the sales filing of Class II medical devices within their respective jurisdictions	Responsible for the routine supervision and management of medical device distributors and medical institutions within their respective jurisdictions	Guide and supervise the regulation conducted by regulatory authorities at the county level in sales and use of medical devices within their respective jurisdictions
Regulatory Authorities at County Level	Responsible for the routine supervision and management of medical device distributors and medical institutions within their respective jurisdictions			

3. The medical device regulation in the whole life cycle has been continuously strengthened

01

Enrich post-marketing regulatory means

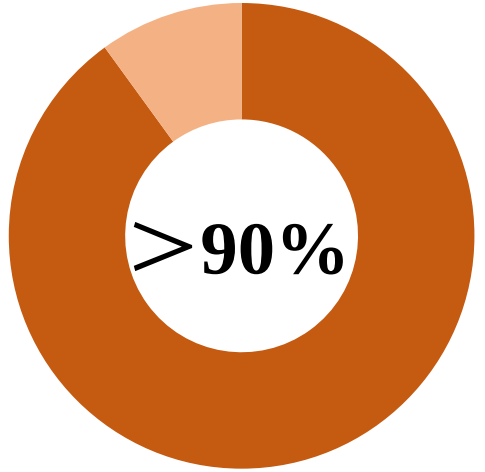
- GMP and GSP inspection
- Monitoring of e-commercial sales
- Supervisory sampling testing
- Adverse event monitoring
- Crackdown on illegal acts

4. The foundation of medical device regulation has been further consolidated

- There are 261 national standards and 1,703 industry standards at present, basically covering all professional and technical fields of medical devices in China.

- 22 guidelines for nomenclature have been issued to guide standardized nomenclature.

Consistency with international standards



4. The foundation of medical device regulation has been further consolidated

The efficiency of classification management of medical devices has been continuously improved

A

Issue the *Opinions on Further Strengthening and Improving the Classification Management of Medical Devices* to strengthen the top-level design

B

Revise the *Rules for Classification of Medical Devices*

C

Dynamically adjust the *Classification Catalogue of Medical Devices*

D

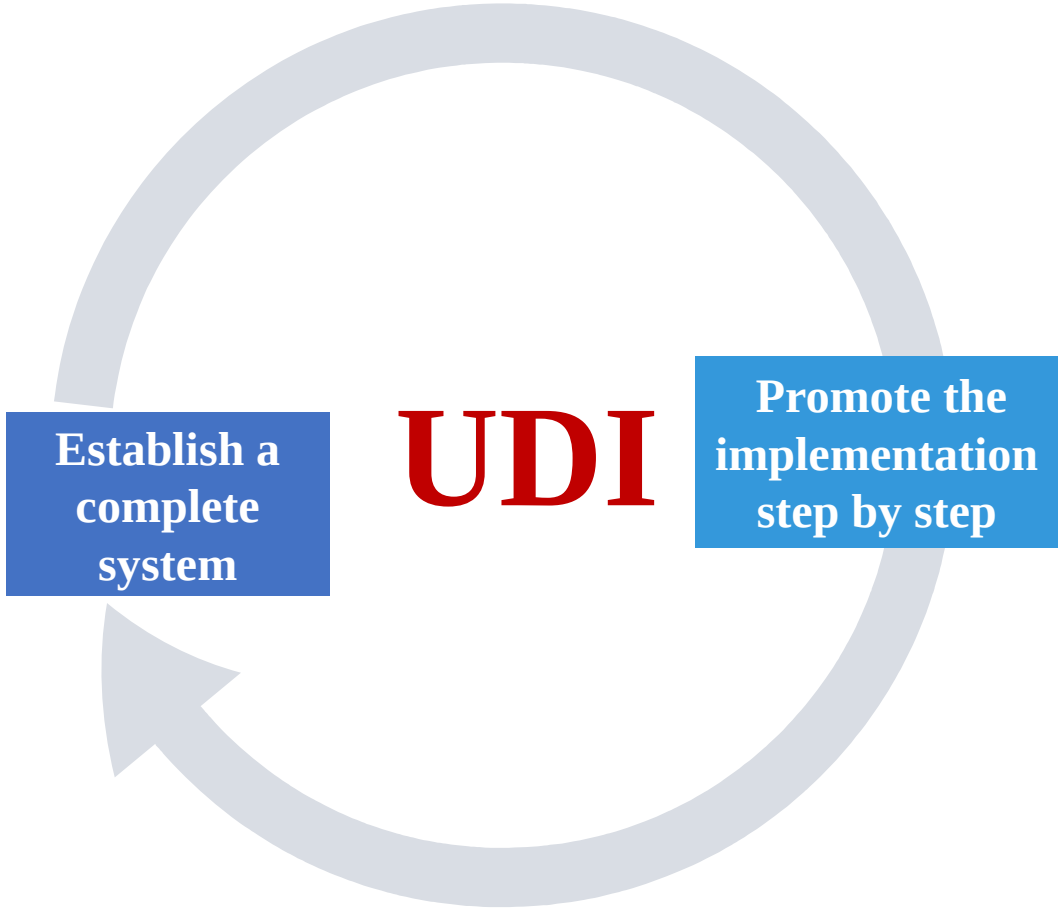
Issue the *Rules for Classification of In Vitro Diagnostic Reagents*

E

Revise the *Classification Catalogue of In Vitro Diagnostic Reagents*

4. The foundation of medical device regulation has been further consolidated

- *Regulations for the Supervision and Administration of Medical Devices* and its supporting provisions
- Rules for Unique Device Identification System
- 5 industry standards
- Unique Device Identification Database (UDID)

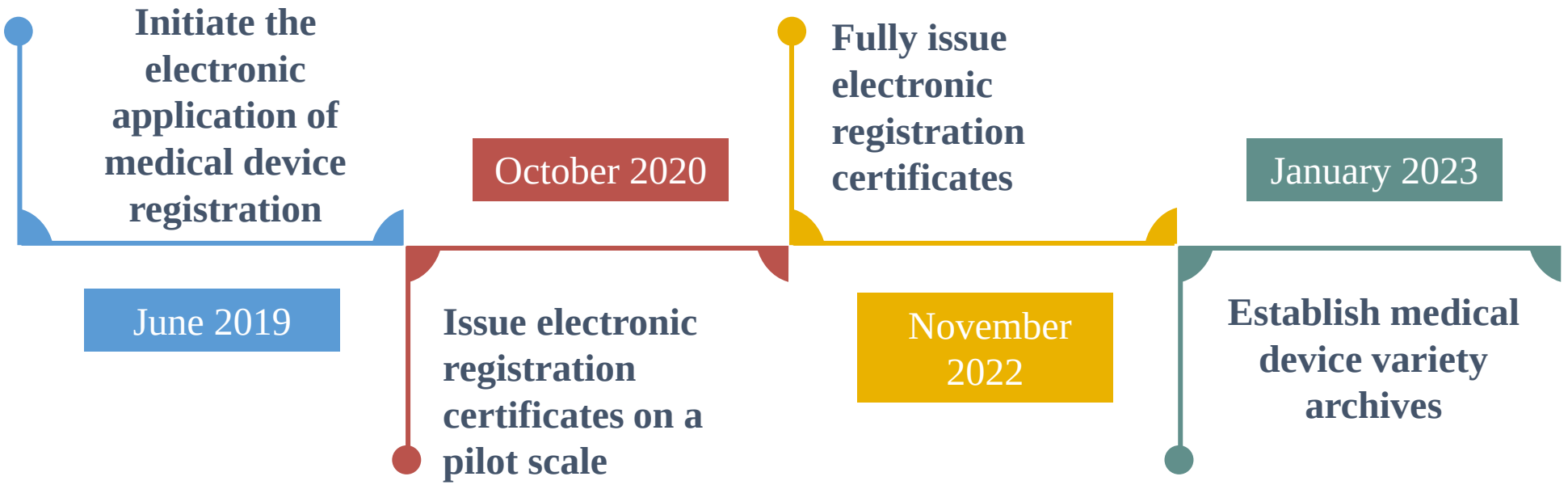


The 1st batch (January 1, 2021): 69 varieties in 9 categories

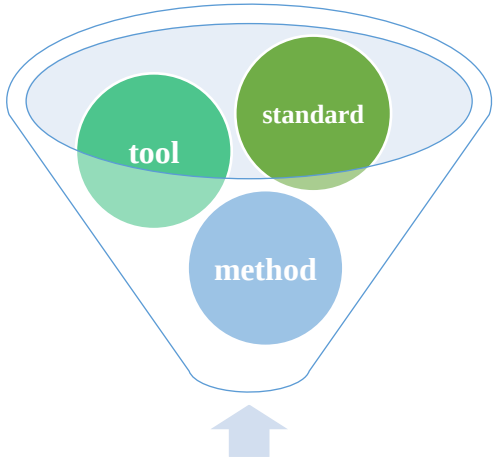
The 2nd batch (June 1, 2022): Other Class III medical devices (including in vitro diagnostic reagents) except the 69 varieties in the 1st batch

The 3rd batch (June 1, 2024): 103 Class II medical devices based on risk leval and regulatory needs

4. The foundation of medical device regulation has been further consolidated



5. The research of medical device regulatory science has been continuously promoted



Initiate China's Action Plan on Drug Regulatory Science and implement the first batch of key projects (4)

April 2019

Initiate the implementation of the second batch of key projects (6)

June 2021

6. The international exchanges and cooperation in medical device regulation have been deepened

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IMDRF International Medical Device Regulators Forum

- Actively participate in ISO and IEC activities.

THANK YOU!