

Medical Device Regulatory Updates in China

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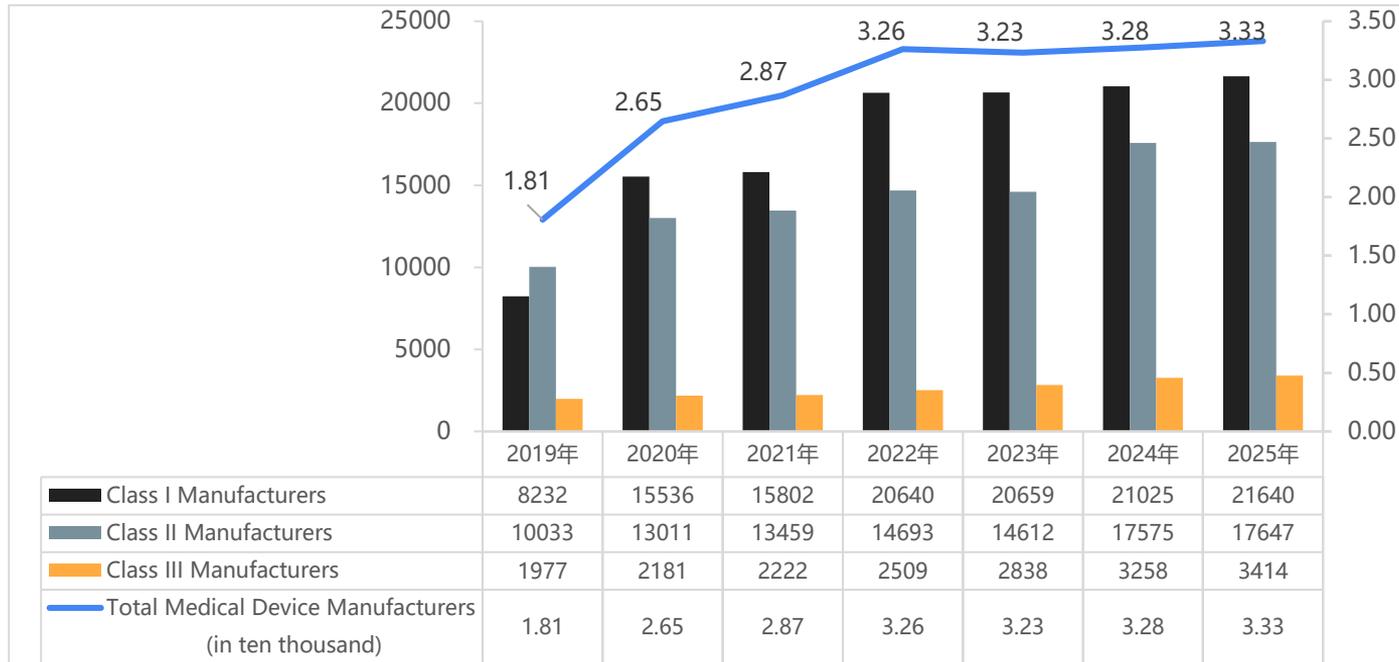


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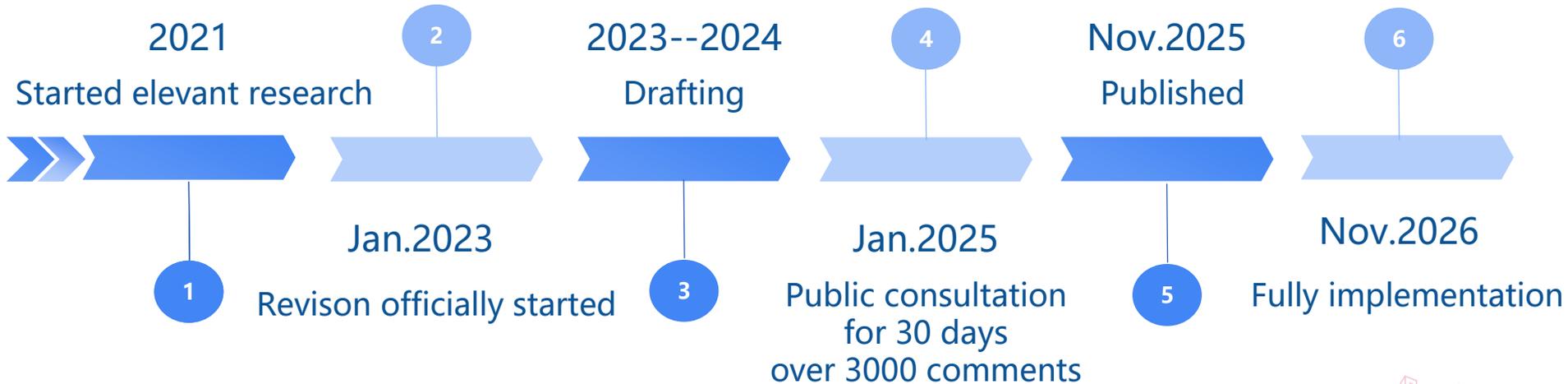


Domestic Medical Device Manufacturers in China, 2019–2025



Revision of the GMP

Revision Process of 3rd Ed. GMP



Revision of the GMP

Optimizing the Regulatory System Structure

Framework Expansion

Total Chapters

8 ▶ 15

Total Articles

84 ▶ 132

New Additions & Gaps Filled

- ✓ **3 New Independent Chapters**
Quality Assurance, Validation & Verification, Contract Manufacturing.
- ✓ **Addressing New Business Models**
Filling regulatory gaps for digital, intelligent manufacturing, and contract services.



Revision of the GMP

Empowering Digital & Intelligent Transformation



Core Principle Innovation

First time encouraging digital transformation as a core regulatory principle, setting clear statutory requirements for data management in production.



Mandated ALCOA+ Principles

Enterprise electronic records must strictly comply with ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, etc.) for lifecycle compliance.



Recognized Digital Technologies

Recognizes compliant application of smart monitoring and e-batch records, standardizing access control, audit trails, and data backup obligations.



Global Regulatory Alignment

Achieves precise alignment with international digital regulatory rules for medical devices, significantly reducing the international compliance costs for market entities.



Dynamic Adjustment of the Classification Catalogue of Medical Devices



Annual Adjustment Mechanism

Established a dynamic mechanism with 1-2 rounds of adjustments per year to enhance regulatory flexibility and scientificity.



2025 Major Update

Implemented optimized adjustments for 31 categories across 10 sub-catalogues, clarifying regulatory boundaries and definitions.



Risk-Based Supervision

Core principle: "High risk, strict supervision; low risk, simplified". Merging or downgrading products based on risk levels.



Global Alignment (IMDRF)

Strictly aligned with IMDRF's "risk-based classification" core principles, facilitating Chinese medical devices entering the global market.



Progress of Industrial Standards for BCI Medical Devices



2 Standards Published

YY/T 1987:Terminology,
YY/T 1996:Test methods for sensing and response performance of implantable neural stimulators with closed-loop function.



3 Standards Initiated

In 2025, NMPA proactively initiated the drafting of 3 key industry standards projects, cover critical aspect:reliability verification of invasive devices and performance testing of RACA robot motion decoding.



Core Areas Coverage

Laying a solid foundation for BCI medical device regulation.
Fill the gaps in segmented fields and construct a holistic standard system.



Revision of Export Sales Certificate Management



Simplified Application Process

Streamlining procedures to reduce redundant steps and improve efficiency for applicants.



Extended Certificate Validity

Increasing the effective period to reduce the frequency of re-application for enterprises.



Legal Effect of e-Certificates

Clarifying that electronic certificates have the same legal status as paper ones.



Enhanced Competitiveness

Reducing institutional transaction costs to boost international market share.



Revision of Export Sales Certificate Management

TYPE I

附件 1

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL
PRODUCTS
(格式)

证书编号
Certificate NO.:

产品名称
Product(s):

规格型号:
Model:

产品注册或备案凭证号:
Registration certificate(s):

生产企业
Manufacturer:

生产企业住所:
Address of manufacturer:

生产许可或备案凭证号:
Manufacturing License(s):

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered
to be manufactured and sold in China.

证明有效期至: 年 月 日
This certification valid until:

备注:
Remark:

年 月 日
(出具单位盖章)

附件 1: (已在我国注册或者备案的医疗器械产品出口销售证明
格式)

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械出口销售证明 (I)
CERTIFICATE FOR EXPORTATION OF MEDICAL DEVICE

证书编号 Certificate No.	(中文) (English)
产品名称 Name of the Product(s)	(中文) (English)
规格型号 Model(s)	(中文) (English)
产品注册或备案凭证号 Registration certificate(s)	(中文) (English)
产品唯一标识码 (UDI)	
医疗器械注册人或 备案人 Legal manufacturer	名称 Name (中文) (English)
	住所 Registered Address (中文) (English)
生产企业 Actual manufacturer	名称 Name (中文) (English)
	生产地址 Facility(s) Address (中文) (English)
	生产许可或备案 凭证号 Manufacturing License (中文) (English)

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured
and sold in China.
出口销售证明作为服务事项出具给中国医疗器械注册人(备案人)。当出口销售证明时,
发证机关将评估该产品是否符合进口国(地区)的要求, 申请人有责任确保遵守这些要求。
The certificate for exportation is issued as a service to the medical device
manufacturer in China. In issuing certificate for exportation, the certifying authority
does not assess or verify that the product complies with the requirements of the importing
country (region). It is the applicant's responsibility to ensure compliance with these

Requirements.	
证明有效期至 This certification valid until	年 月 日 YYYY/MM/DD
备注 Remark	(中文) (English)
发证机关 Certifying authority	(中文) (English) 年 月 日 YYYY/MM/DD (盖章 Stamp)

This is to certify that the above medical device(s) have been approved for manufacture and sale in China. The Certificate for Exportation is issued as a service item to the Medical Device Registration Certificates or Filing Entities in China. The applicants are obligated to comply with the requirements of the importing countries(regions), as the certifying authority does not evaluate or verify if the products comply with the requirements of the importing countries(regions) when issuing the Certificate for Exportation.

Revision of Export Sales Certificate Management

TYPE II

This is to certify that the above medical device(s) have not been approved or filed in China, and are intended for sale outside of China only.

The Certificate for Exportation is issued as a service item to the medical device manufacturers in China. The manufacturers shall meet the production conditions required by the Good Manufacturing Practice for Medical Devices. The applicants are obligated to comply with the requirements of the importing countries(regions), as the certifying authority does not evaluate or verify if the products comply with the requirements of the importing countries(regions) when issuing the Certificate for Exportation.

附件 2：（未在我国注册或者备案的医疗器械产品（含已注册或者备案产品的未注册或者备案的规格型号）出口销售证明格式）

中华人民共和国

PEOPLE'S REPUBLIC OF CHINA

医疗器械出口销售证明（II）

CERTIFICATE FOR EXPORTATION OF MEDICAL DEVICE

证书编号 Certificate No.	(中文) (English)	
产品名称 Name of the Product(s)	(中文) (English)	
规格型号 Model(s)	(中文) (English)	
产品所有者 Product Owner	(中文) (English)	
生产企业 Manufacturer	名称 Name	(中文) (English)
	生产地址 Facility(Address)	(中文) (English)
	生产许可或备案 凭证号	(中文) (English)
	Manufacturing License	(English)

兹证明上述产品未在中国注册，尚未进入中国市场。
This is to certify that the above product(s) are not registered in China and not distributed on the Chinese market.

出口销售证明作为服务事项出具给中国的医疗器械生产企业。该生产企业符合医疗器械生产质量管理规范要求的生产条件。出具出口销售证明时，发证机关未评估或验证产品是否符合进口国（地区）的要求，申请人有责任确保遵守这些要求。

The certificate for exportation is issued as a service to the medical device manufacturer in China. The manufacturer meets the production conditions required by the Good Manufacturing Practice for Medical Devices. In issuing certificate for exportation, the certifying authority does not assess or verify that the product complies with the requirements of the importing country (region). It is the applicant's responsibility to ensure compliance with these requirements.

证明有效期至 This certification valid until	
备注 Remark	(中文) (English)
发证机关 Certifying authority	(中文) (English) 年 月 日 YYYY/MM/DD (盖章 Stamp)

Guiding Principles for Online Sales Inspections



Current Market Scale

360,982 companies selling medical devices online across the country, plus 851 providing third-party platforms for these transactions



Regulatory Policy System

Measures for the Supervision and Administration of Online Sales of Medical Devices (2017)
Quality Management Specifications for Online Sales of Medical Devices (2025)
Guidelines for On-Site Inspection of the Quality Management Specifications for Online Sales of Medical Devices (2025)



Innovative Regulatory Technologies

Building a monitoring platform for online medical device sales and setting up a closed-loop info flow system.



Thank You!

