



首届世界中医药人工智能大会

The 1st World Congress on Artificial Intelligence in TCM



List of Compliance Requirements for Exhibited Products

To ensure compliance with exhibition regulations, please prepare the relevant documents strictly according to the following categories. All documents must be genuine, valid, and within their validity period. This form provides a detailed list of qualification requirements for various product categories, including pharmaceuticals, medical devices, food-as-medicine products, and AI-powered intelligent agents.

Comprehensive Table of Qualification Compliance Requirements

Exhibit Category	Corporate Qualifications (Entry Requirements)	Product Listing Qualifications (One Product, One Certificate)	Special Requirements for Imported Products
Pharmaceuticals (incl. TCM Decoction Pieces/Finished Drugs)	<ol style="list-style-type: none"> Business License (Three-in-One) Drug Production License (Manufacturer) or Drug Distribution License (Distributor) GMP/GSP Compliance Inspection Results 	<ol style="list-style-type: none"> Drug Registration Certificate (National Drug Approval Document) Recent Drug Inspection Report Filed Package Insert and Labels 	<ol style="list-style-type: none"> Import Drug Registration Certificate Import Drug Customs Clearance Form Port Drug Inspection Institute Report
Medical Devices (incl. Equipment/ Consumables/ Reagents)	<ol style="list-style-type: none"> Business License Production/Distribution License (Class I & II Filing, Class III Permit) 	<ol style="list-style-type: none"> Medical Device Registration Certificate (or Filing Certificate) Product Technical Requirements Specification Software Version Statement (if software is included) 	<ol style="list-style-type: none"> Import Medical Device Registration Certificate Manufacturer Authorization Letter & Customs Declaration Chinese Labels and Package Inserts
Medicine & Food Homology Products (General Food Category)	<ol style="list-style-type: none"> Business License Food Production License (SC Certificate) or Food Operation License 	<ol style="list-style-type: none"> Third-party Test Report (issued within the last year, including heavy metals & microbiology) Product Implementation Standard (Enterprise Standard or National Standard) Strictly prohibited to claim therapeutic efficacy 	<ol style="list-style-type: none"> Entry-Exit Inspection and Quarantine Certificate Import Customs Declaration Form Certificate of Origin
Medicine & Food Homology Products (Health Food Category)	<ol style="list-style-type: none"> Business License Food Production / Operation License 	<ol style="list-style-type: none"> Health Food Registration Certificate (or Record-filing Certificate) Health Food Logo (“Blue Hat”) and Approval Number 	<ol style="list-style-type: none"> Import Health Food Approval Certificate Inspection and Quarantine Certificate



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Exhibit Category	Corporate Qualifications (Entry Requirements)	Product Listing Qualifications (One Product, One Certificate)	Special Requirements for Imported Products
AI Agents (Medical AI / Software)	1. Business License (must include software development/sales scope) 2. Software Copyright Certificate	1. If used for diagnosis/treatment: Must provide Medical Device Registration Certificate (usually containing AI software components) 2. If for assistance/management only: Must provide Software Test Report and Function Manual 3. Data Security and Privacy Compliance Statement	1. Certificate of Foreign Listing (Proof of marketing in country of origin) 2. Chinese Localization Deployment Description 3. Cross-border Data Transmission Compliance Proof (if applicable)

Special Notice

1. One Product, One Certificate Principle

Every specific model and specification of the product on display must have its corresponding Registration Certificate or Filing Record.

2. Promotion Compliance Requirements

Drugs/Medical Devices: Promotional content must strictly align with the approved scope of application on the Registration Certificate. Exaggerated claims are prohibited.

Medicine and Food Homology: Medical terminology such as “treatment,” “cure,” or “therapeutic efficacy” is strictly prohibited. Violations will be classified as non-compliant advertising.

3. On-Site Inspection Readiness

Please carry the **original documents** or **photocopies stamped with the official company seal** for all certificates to facilitate surprise inspections by on-site market regulators.

4. Important Notes

- (1). All certificates must be valid.
- (2). Import-related procedures must be completed in advance for imported products.
- (3). For AI Agent products, clearly define their functional positioning and select the appropriate



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regulatory pathway.

(4). In case of any doubts, it is advisable to consult local regulatory authorities in advance.

All participating units are requested to strictly prepare relevant qualification documents in accordance with these requirements to ensure the compliant and smooth operation of the exhibition. For special circumstances, please communicate and coordinate with the exhibition organizer in advance.