Measures for the Administration of Inspection and Supervision of the Imported Medical Instruments[1]

Authority: **State Administration of Quality Supervision, Inspection & Quarantine (dissolved)**

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Chapter I: General Provisions

Article 1

These Measures are formulated in accordance with the *Law of the People's Republic of China on the Inspection of Import and Export Commodities* ("Inspection Law"), its implementing regulations, and other relevant laws and administrative regulations, for the purpose of strengthening the administration of inspection and supervision of imported medical devices and safeguarding human health and life safety.

Article 2

These Measures shall apply to the following aspects of imported medical devices:

(a) Categorized administration of medical device importers;

(b) Inspection and supervision of imported medical devices;

(c) Risk prevention and rapid response management concerning imported medical devices.

Article 3

The General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China ("GAQSIQ") shall be responsible for nationwide administration, organization, collection, and assessment of risk-related information concerning imported medical devices,

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

and for the implementation of corresponding risk prevention and emergency response measures.

The entry-exit inspection and quarantine authorities established by the GAQSIQ ("IQ agencies") shall be responsible for the local inspection and supervision of imported medical devices within their respective jurisdictions. They shall also be tasked with collecting and analyzing risk information, conducting risk assessments, and implementing appropriate preventive and response measures.

Chapter II: Categorized Supervision of Medical Device Importers

Article 4

IQ agencies shall implement a three-tier categorized supervision system for medical device importers, based on the importers' management standards, credibility, and the risk level, quality, and import volume of the devices in question.

Medical device importers may voluntarily apply for inclusion in a specific category under the categorized management framework.

Article 5

Importers classified under Category A shall meet the following requirements:

(a)Full compliance with the Inspection Law, its implementing regulations, and other relevant laws, administrative regulations, and GAQSIQ provisions, with no record of non-compliance for five consecutive years;

(b) Possession of a robust quality management system certified under ISO9000 and comprehensive internal procedures for import declarations, inspections, storage, quality monitoring, defect reporting, etc.;

(c) Employment of at least two qualified quality management personnel, certified by an IQ agency, with sufficient technical knowledge of the relevant devices and understanding of the regulatory inspection framework in China;

(d) Possession of valid certification for handling devices subject to mandatory product certification;

(e) A record of high-quality imported products with no recalls, damage claims, or other product liability incidents in the past two years;

(f) Continuous operation of medical device importation for at least six years, with supporting documentation;

(g) Importation of no fewer than 30 batches annually over the previous two years;

(h) Maintenance of relevant national and industrial standards, applicable laws, and regulations for medical devices, and complete technical documentation retained for at least 10 years;

(i) Adequate technical training and after-sales service capability, or third-party technical support arrangements;

(j) Possession of independent business premises and suitable storage facilities commensurate with the nature and scale of the imported devices.

Article 6

Importers classified under Category B shall meet the following requirements:

(a)General compliance with applicable laws and regulations, with no record of non-compliance for three consecutive years;

(b) A functioning quality management system with procedures for import declaration, inspection, storage, defect reporting, and follow-up;

(c) Employment of at least one trained and certified quality management personnel familiar with the technical features of the devices and regulatory inspection processes;

(d) Valid certification for dealing in devices subject to mandatory product certification;

(e) No recalls, damage claims, or product liability incidents within the past year;

(f) At least three years of continuous operation in the medical device import business, with documentation;

(g) Importation of no fewer than 10 batches annually over the previous two years;

(h) Maintenance of applicable standards and documentation for at least 10 years;

(i) Technical training and after-sales service capability, or contracted third-party support; and

(j) Independent premises appropriate to the scale and complexity of their operations.

Article 7

Importers classified under Category C include:

(a)Importers with less than three years of operational history;

(b) Importers with more than three years of history who have not applied for categorized management;

(c) Importers who applied for categorization but failed to qualify for Category A or B.

Article 8

An importer applying for classification under Category A or B ("applicant") shall submit an application to the inspection and quarantine administration directly under the GAQSIQ at its place of registration, along with the following materials:

(a)A written application bearing the authorized signature and official seal;

(b) Business license and medical device operation permit;

(c) ISO quality system certification and internal quality management documentation;

(d) Certificates of training and qualification of quality personnel issued by an IQ agency;

(e) Documentation verifying the number of import batches in the last two years; and

(f) A declaration of compliance with applicable laws and truthfulness of the submitted materials.

Article 9

The local inspection and quarantine authority under the GAQSIQ shall review the application documents within five working days. In case of incomplete documentation, the applicant shall be notified to supplement the submission.

For Category A applications, upon document review, an on-site inspection shall be organized. If passed, the results and supporting materials shall be submitted to the GAQSIQ for final review and approval. The GAQSIQ shall periodically publish the list of Category A importers.

For Category B applications, the local inspection authority may conduct the on-site inspection or delegate it to the relevant IQ agency. Upon passing inspection, the authority shall approve the application and report it to the GAQSIQ for recordkeeping. The list of Category B importers shall be periodically published by the authority.

Chapter III: Risk Levels and Supervision of Imported Medical Devices

Article 10

IQ agencies shall implement inspection and supervision protocols—including on-site inspection and follow-up monitoring—based on the risk level of the imported medical devices and the importer's classification, in accordance with GAQSIQ provisions.

Article 11

The GAQSIQ shall classify imported medical devices into three risk levels based on structural characteristics, application scenarios, relevant national categorization rules, and import inspection needs:

-High Risk

-Relatively High Risk

-Ordinary Risk

A catalogue specifying the risk levels of imported medical devices shall be formulated, adjusted as necessary, and published no less than 60 days prior to its effective date.

Chapter IV: Risk Classification and Inspection Supervision of Imported Medical Instruments

Article 12

Imported medical instruments falling under any of the following categories shall be classified as high-risk:

(a)Implantable medical instruments;

(b) Powered instruments designed to intervene within the human body;

(c) Instruments intended for life support or vital function maintenance;

(d) Medical imaging or therapeutic energy devices that pose potential hazards to human health;

(e) Instruments with unstable product quality, associated with multiple serious quality incidents, and requiring stringent safety and efficacy control.

Article 13

Imported medical instruments falling under any of the following categories shall be classified as relatively high-risk:

(a) Non-powered instruments used for internal human body intervention;

(b) Other powered instruments that contact the human body but do not meet the threshold for high-risk classification;

(c) Instruments with unstable quality, associated with multiple quality issues, and requiring controlled safety and performance monitoring.

Article 14

All imported medical instruments not classified as either high-risk or relatively high-risk shall be designated as ordinary risk.

Article 15

High-risk medical instruments shall be subject to the following inspection and supervision regime:
(a) For Category A importers: a combined model of on-site and supervisory inspection shall be applied, with on-site inspection conducted on not less than 50% of all import batches annually;

(b) For Category B and C importers: every import batch shall undergo on-site inspection.

Article 16

Relatively high-risk medical instruments shall be subject to the following inspection regime: (a) For Category A importers: on-site inspections shall cover at least 30% of import batches annually;

(b) For Category B importers: at least 50% of import batches shall be inspected annually;

(c) For Category C importers: on-site inspection shall be conducted for each batch.

Article 17

Ordinary risk medical instruments shall be subject to combined on-site and supervisory inspection, with minimum on-site inspection rates as follows:

(a)Category A importers: 10% annually;

(b) Category B importers: 30% annually;

(c) Category C importers: 50% annually.

Article 18

Where deemed necessary, the GAQSIQ may organize production supervision, pre-shipment inspection, and installation oversight of high-risk medical instruments, in accordance with relevant foreign trade contract provisions.

Article 19

Upon import, the consignee or its authorized agent (the “inspection declarant”) shall submit an inspection declaration to the IQ agency at the customs location, along with:

(a)Required inspection documentation;

(b) Certificate of China Compulsory Certification (CCC), if applicable;

(c) Registration certificate issued by the State Council’s drug supervision authority;

(d) Proof of importer classification (Category A or B) issued by the relevant IQ agency.

Article 20

The customs IQ agency shall review submitted documentation. If incomplete or non-compliant, the inspection declarant shall be notified. Upon approval, a Notice of Customs Clearance for Inbound Goods shall be issued. Once customs clearance is completed, the importer shall promptly apply for inspection with the IQ agency.

Article 21

Imported medical instruments shall be inspected at the destination site specified in the inspection declaration.

For instruments requiring installation or adjustment for inspection, the place of use must be declared, and the IQ agency at that location shall carry out the inspection. The GAQSIQ shall publish and enforce a catalogue of instruments subject to this requirement.

Special products, such as implantable devices, shall be inspected by IQ agencies designated by the GAQSIQ.

Article 22

IQ agencies shall inspect imported medical instruments in accordance with mandatory national technical standards. If no such standards exist, relevant foreign standards designated by the GAQSIQ may be used as reference.

Article 23

On-site and supervisory inspections may include, but are not limited to:

(a)Verification of product-certificate consistency;

(b) Confirmation of quantity, specifications, type, and appearance;

(c) Review of packaging, labeling, and signs, including quarantine for wooden materials;

(d) User manuals and accompanying documentation;

(e) Assessment of mechanical, electrical, and electromagnetic safety;

(f) Examination of radiation, noise, and biochemical safety aspects;

(g) Evaluation of toxic or hazardous emissions, residues, and materials;

(h) Performance evaluation for diagnostic or therapeutic functions;

(i) Compliance with Chinese labeling and instruction requirements.

Article 24

For instruments subject to mandatory certification, IQ agencies shall:

– Inspect certificates,

– Examine documentation,

– Verify consistency between goods and certificates,

– If needed, collect samples for laboratory testing in accordance with state standards and the mandatory certification system.

Article 25

If the instruments pass inspection, the IQ agency shall issue a Certificate of Inspection and Quarantine for Inbound Goods.

If found non-compliant, a Notice of Inspection and Quarantine Treatment shall be issued. Where damages are involved, an inspection certificate shall be provided. If the non-conformity poses risks to human safety, health, or the environment, and cannot be rectified, the IQ agency shall order destruction or return of the goods, notify customs, and report the matter to the GAQSIQ.

Chapter V: Supervision of Donated Medical Instruments

Article 26

Donated medical instruments must be unused and free from environmental, health, or other hazardous contaminants.

Article 27

Importation of donated instruments listed in the Catalogue of Prohibited Imports is strictly forbidden.

Article 28

Overseas donors, or their China-based agents, must file information on both the donating institution and the donated instruments with the GAQSIQ.

Article 29

If necessary, the GAQSIQ may arrange pre-shipment inspections of donated medical instruments.

Article 30

The receiving entity or its agent must file an inspection declaration with the IQ agency at the customs point and apply for inspection at the place of use, based on valid authorizing documentation.
The IQ agency shall conduct customs and destination inspections based on these documents.

Article 31

Donated medical instruments may only be put to use upon passing inspection and issuance of a Certificate of Inspection and Quarantine. If found non-compliant, the instruments shall be disposed of in accordance with applicable law.

Chapter VI: Risk Prevention and Emergency Response

Article 32

The GAQSIQ shall establish a risk prevention mechanism for imported medical instruments. Based on gathered risk information, the GAQSIQ may issue alerts and take precautionary and emergency measures per applicable regulations.

Article 33

IQ agencies shall regularly collect information on the performance and quality of imported medical instruments in use, and promptly report any major quality incidents to the GAQSIQ.

Article 34

Manufacturers, importers, and users must report any defects in imported instruments to IQ agencies and cooperate in the implementation of precautionary and emergency measures.

Article 35

Precautionary measures for defective instruments may include:

(a)Issuing alerts to IQ agencies to intensify inspection of specific manufacturers or importers;

(b) Notifying producers/importers to take corrective action;

(c) Issuing public warnings to users and consumers;

(d) Reporting to domestic authorities, foreign embassies, international organizations, and recommending appropriate countermeasures.

Article 36

Emergency response measures may include:

(a)Advising suspension of product use;

(b) Reclassifying the importer's category;

(c) Halting further importation of the defective products;

(d) Suspending or revoking compulsory certification;

(e) Any other necessary interventions.

Chapter VII: Supervision and Management

Article 37

IQ agencies must conduct an annual supervisory assessment of Category A and B importers. An importer may be downgraded if any of the following circumstances are found:

(a) Poor credibility record;

(b) Imported medical instruments present serious safety risks or significant quality issues;

(c) 10% or more of the importer's annual batches fail inspection;

(d) Import volumes fall below required thresholds;

(e) Any violation of applicable laws or regulations.

Downgraded importers may apply for reclassification after 12 months, subject to reexamination and approval by the IQ agency, followed by an official announcement.

Article 38

With approval from its leadership, an IQ agency may seize or detain imported medical instruments (excluding those under customs supervision) if:

(a) The products are prohibited from importation;

(b) They pose safety, health, or environmental hazards;

(c) They present immediate danger to life or property of users or patients.

Article 39

GAQSIQ shall be responsible for the training and certification of IQ agency personnel involved in inspecting imported medical instruments. Only certified personnel may engage in inspection and supervisory work.

Article 40

Used medical instruments intended for non-patient purposes (e.g., research) may only be imported with prior approval from GAQSIQ and other relevant authorities.

Re-manufactured medical instruments from original manufacturers may be imported only if they meet all safety and technical standards required for new products, pass an IQ agency assessment, and receive GAQSIQ approval.

All other used medical instruments are strictly prohibited from being imported.

Chapter VIII: Legal Liability

Article 41

If medical instruments subject to mandatory inspection are sold or used without proper declaration or inspection, or are not verified as required, the IQ agency may:

-Confiscate the illegal income;

-Impose a fine between 5% and 20% of the product's value;

-Refer the case for criminal liability if applicable.

Article 42

If unqualified imported medical instruments are sold or used, the IQ agency shall:

-Order immediate cessation of sale/use;

-Confiscate the illegal income and products;

-Impose a fine up to three times the product's value;

-Refer the case for criminal prosecution, if necessary.

Article 43

Importers of prohibited used medical devices must return or destroy them per state regulations. If the products are electromechanical and the violation is serious, a fine up to 1 million yuan may also be imposed.

Article 44

IQ agency personnel guilty of misconduct—including abuse of power, bribery, falsification of results, or delay in inspections—will face disciplinary action. Criminal liability applies where relevant.

Chapter IX: Supplementary Provisions

Article 45

"Imported medical instruments" refer to any equipment, device, material, or software brought into China for use on the human body, for purposes such as diagnosis, treatment, care, prevention, physiological monitoring, or birth control.

"Defective medical instruments" are those that fail to meet national standards or pose unreasonable safety risks.

"Importer" refers to a Chinese legal entity that signs a foreign trade contract or appoints an agent to import medical instruments.

Article 46

These Measures also apply to medical instruments entering from customs supervision zones (e.g., bonded areas) or moved from such zones to inland areas in China.

Article 47

These Measures apply by analogy to imported veterinary medical instruments.

Article 48

Imported medical instruments classified as boiler pressure vessels or measuring instruments must comply with the GAQSIQ's safety supervision and measurement laws.

Article 49

The GAQSIQ is responsible for interpreting these Measures.

Article 50

These Measures are effective from December 1, 2007.