HEALTH SERVICE
HO CHI MINH CITY
INSPECT

Number: 1150/TTra-D
Regarding the notice of inspection of the implementation of legal regulations in the field of medical devices

SOCIALIST REPUBLIC OF VIETNAM
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Ho Chi Minh City, July 4, 2024

To: Asia Actual VietNam Co., Ltd

Pursuant to Decision No. 2810/QD-SYT dated May 8, 2024 of the Director of the Department of Health on the establishment of a Team to inspect compliance with legal regulations in production, import-export, trading and management. management and use of medical equipment in Ho Chi Minh City;

The Department of Health inspection team will inspect the activities of companies involved in the production, import, export, purchase, sale, management and use of medical equipment (abbreviated as TBYT) in the City. Ho Chi Minh.

Time, location, and members of the inspection team:

- Inspection period: July 15, 2024 to December 31, 2024.

- Inspection location: at the inspected company.

- Reception members: Company legal representative, technical officer.

The inspection team requested the company to prepare a written report and provide attached documents with the following specific contents:

I. Written report summarizing the company's operations related to production, import, export, purchase, sale, management and use of medical equipment:

1. Legal documents

- Business registration certificate;

- Other legal documents (if any).

2. For documents declaring eligibility to produce medical equipment (if any)

- Documents declaring the facility's eligibility to produce medical equipment; Receipt of dossier declaring eligibility to produce medical equipment from the State management agency;

- Valid certificate of ISO 13845 quality management standards;

- The qualifications of the person in charge of the profession meet the regulations;

- Staff profile meets production requirements for the type of medical equipment the facility produces;

- Personnel organization profile; labor contracts, job descriptions for each position, documents clearly stating the responsibilities and relationships of each employee;

- Documents for purchasing raw materials and inputs for production;

- Documents on conditions of facilities and equipment: Conditions on production workshops, storage warehouses, ensuring labor safety, fire and explosion prevention, waste and wastewater treatment systems;

- Other relevant records.

3. For standard publication numbers of medical devices of type A and B

- Standard publication number applicable to medical equipment of types A, B. Document announcing standards applicable to medical equipment types A, B,

- Certificate of eligibility for medical equipment warranty;

- Power of attorney from the owner of the medical equipment to the organization that announces the standards;

- Receipt of dossier declaring eligibility for production of domestically produced medical equipment or Certificate of quality management standards still valid at the time of submitting the declaration dossier for imported medical equipment;

- Documents proving compliance with national standards or standards announced by the manufacturer;

- Valid certificate of ISO 13845 quality management standards;

- Technical documents: Documents describing technical briefs; Label sample used when circulating in Vietnam; Instructions for use; Testing results of the product before circulation; Certificate of free sale (CFS) is still valid for imported medical equipment.

4. For documents declaring eligibility to buy and sell medical equipment

- Receipt form;

- Personnel declaration sheet;

- Records on storage of medical equipment;

- Documents on means of transporting medical equipment;

- Other related records.

5. For circulation registration numbers or import licenses of medical equipment of type C and D issued by the Ministry of Health (if any)

- Document requesting a new circulation number.

- Valid certificate of ISO 13845 quality management standards.

- Authorization letter from the owner of the medical device for the facility to register for circulation.

- Warranty eligibility certificate issued by the owner of the medical equipment, except in the case of single-use medical equipment according to the regulations of the medical equipment owner or there are documents proving that there is no warranty. warranty level.

- Valid circulation certificate for imported medical equipment.

- General technical dossier on medical equipment according to ASEAN regulations (hereinafter abbreviated as CSDT dossier).

- Certificate of conformity.

6. For medical equipment imported by the company

- Documents related to the import process: Import contract; customs declaration; Certificate of origin (C/O) and product quality certificate (C/Q); bill of lading; purchase invoice from abroad (invoice);

- Other related documents: Contract and purchase invoice between the importing enterprise and the winning enterprise in case the unit does not directly import; Handover records, acceptance, invoices, liquidation of equipment contracts provided.

7. For medical equipment distributed (purchased and sold) by the company

- Number of applicable standards publication or circulation registration, medical equipment price declaration information.

- Invoice documents for distribution.

- Traceability and warranty records; Instructions for use, conditions to ensure safety, storage, calibration, inspection, maintenance, and upkeep of medical equipment.

8. Making false declarations of medical equipment

Photocopy of fake medical declaration information on the Ministry of Health's electronic portal.

9. Medical device advertising

Certificate of confirmation of medical equipment advertising content and content requested for advertising confirmation approved by the Ministry of Health (if any).

II. List of products produced, imported and traded (according to form)

Follow the form provided by the inspection team.

III. Records and attached documents

- Written report summarizing the company's operations - related to production, import, export, purchase, sale, management and use of medical equipment (original and stamped and signed by the legal representative) law).

- List of products produced, imported and traded (original and stamped and signed by legal representative).

- Business registration certificate (copy with company seal).

- Degree of the person in charge of medical equipment (photocopy with company stamp).

- ISO 13485 paper; Consularly legalized Power of Attorney in the host country (LOA); Certificate of Free Circulation (CFS) (photocopy and stamp and signature of legal representative).

In order for the inspection process not to affect the company's operations and to create favorable conditions for the inspection team to complete its tasks, inspected establishments are required to prepare full written reports and financial records. Attached documents depend on the actual operations of the facility.

Upon receiving this notice, the facility is requested to provide feedback to the Medical Equipment Department of the Department of Health Inspectorate within the time frame from 2:00 p.m. to 4:00 p.m. (working days of the week) via phone number 02839301149 for specific instructions and notifications.

Note:

In case the authorized person receives the Inspection Team, the legal representative of the Company must authorize in writing signed and stamped. The authorization document

contains the following content: work with the Inspection Team, record records of administrative violations and exercise the enterprise's right to explain according to the law on handling administrative violations (if any).

Receiving place:
- As above;
- Filed: VT, KTra delegation.

CHIEF INSPECTOR

Ho Van Han

LIST OF MEDICAL EQUIPMENT THE COMPANY IS PRODUCING, IMPORTING AND TRADING

No	Trade name	Name of medical device	Health insurance code	Manufacturer	Global Medical Device Nomenclature Code – GMDN	Product code	Generic	Publication number or registration number	Name of owner of TBYT	Name of circulation number owner	Import price	Declared price	Declared price	Highest selling price	Lowest selling price	Note
A. Receiving number announcing standards for applying Class A medical equipment																
1																
2																
3																
4																
...																
B. Number of receipt of declaration of standards for application of type B medical equipment																
1																
2																
3																
4																
...																
C. Registration number for circulation of type C and D medical equipment																
1																
2																
3																
4																
...																
D. License to import medical equipment issued by the Ministry of Health																
1																
2																
3																

4															
...															