

HEALTH SERVICE
HO CHI MINH CITY
INSPECTION TEAM
Number: 158/BBKT

**SOCIALIST REPUBLIC OF
VIETNAM**
Independence - Freedom - Happiness

MINUTES OF MEDICAL EQUIPMENT INSPECTION

Today, at 9:00 a.m. on August 14, 2024; The inspection team was established in Decision No. 2810/QD-SYT dated May 8, 2024 of the Director of the Department of Health. Establishment of an inspection team on compliance with legal regulations in production, import, export, and trading and management and use of medical equipment in Ho Chi Minh City.

Members of the inspection team include :

1. Mr. Le Tuan Anh
– Deputy Head of delegation;
2. Ms. Tran Thi Dieu Ai - Member;
3. Ms. Mai Thi Le Trinh - Member;
4. Mr. Ha The Binh
- Member.

Conducted inspection : ASIA ACTUAL VIETNAM COMPANY LIMITED

- Head office address: 45/90 Binh Tien, Ward 7, District 6, Ho Chi Minh City
- Legal representative of the company: Mr. Vo Trung Viet

Members of the Receiving Delegation:

Mr. Vo Trung Viet - Director – 0969 159 420

I. TEST CONTENT AND RESULTS

1. Inspection content

Check compliance with legal regulations in the production, import, purchase, sale, management and use of medical equipment (abbreviation: TBYT).

2. Announcement of inspection decision

The Inspection Team representative announced and read the full text of the above Decision, introduced the Inspection Team members, and announced the working plan between the Inspection Team and the Company.

3. Test results

3.1. Legal records of the company

- Business registration certificate No. 0316765196 issued by the Department of Planning and Investment

Ho Chi Minh City issued for the first time on March 23, 2021; 2nd change March 15, 2023;

3.2. Documents published on the online public service system for medical equipment management

ASIA ACTUAL VIETNAM COMPANY LIMITED is the owner of the circulation number with 93 numbers

Receive Announcement and issue new circulation numbers for Medical Devices.2

- New issuance of circulation numbers for other medical equipment (imported type C and D equipment): 09

Certificate of Circulation.

- Information Document declaring eligibility to buy and sell medical equipment of type B: 71 numbers

reception

- Information of dossier announcing applicable standards of type A medical equipment: 12 continued numbers

receive;

- Declaration of eligibility to purchase and sell medical equipment: 01.

3.2.1. For dossiers announcing eligibility to purchase and sell medical equipment of type B,

C, D:

- Information of dossier declaring eligibility to buy and sell medical equipment of type B, C, D:

Announcement number: 220000463/PCBMB-HCM, announcement date: March 17, 2022, by the Department of Health

Ho Chi Minh City receives, specifically:

+ Personnel declaration includes: 01 employee;

+ Documents proving storage warehouses and means of transportation: Records of storage warehouses

Manage and record appropriate means of transport as published on the service system online medical equipment management tool.

+ Documents proving the storage warehouse, monitoring system and management of the XNT process

warehouse of medical equipment containing narcotics and precursors (if any): **The**

company does not trade medical equipment containing narcotics and precursors.

Documents announcing eligibility to buy and sell are consistent with published documents.

3.2.2. For documents declaring eligibility to produce medical equipment: The company does not do so

3.2.3. For dossier announcing applicable standards of medical equipment of type A or B:

The delegation checked the documents in the LIST OF FORMULATIONS ON THE GENERAL PAGE

ONLINE PUBLIC SERVICE SYSTEM MANAGEMENT OF PUBLIC MEDICAL EQUIPMENT

ASIA ACTUAL VIETNAM CO., LTD according to the numbers 2, 5, 12, 17, 26, 37, 39 57, 77, 89:

At the time of inspection, Mr. Vo Trung Viet had not prepared the original documents of the products

Products according to the order numbers listed above because the Company only has 01 employee, please present all original documents that have been published on the online public service system for medical equipment management in Thanh Hoa. Check Ho Chi Minh City Department of Health.

3.3. Implementation of regulations on import and trading of medical equipment

At the time of inspection, the company reported the import, production and trading of medical equipment as follows:

3.3.1. Import:

ASIA ACTUAL VIETNAM COMPANY LIMITED only imports the product "Software medical image storage and transmission" belongs to the announcement of standards for applying type B medical equipment with reception numbers 220002937/PCBB-HCM and 220002938/PCBB-HCM;

The company imports by sending the above products via electronic mail (email), then the Company provides "Medical image storage and transmission software" to customers also via customer email;

The company presented invoice number 00000005 dated December 12, 2022, selling Part SwiftMR software (Model: A20-CL) 1 month trial for Agricultural General Hospital.

3.3.2. Business:

In addition to the “Medical Image Storage and Transmission Software” mentioned above, CO., LTD

ASIA ACTUAL VIETNAM has not yet imported or traded equipment products Health has announced on the online public service portal on medical equipment management.

3.4. Preserving medical equipment

The company has a medical equipment storage warehouse at the address as shown in the announcement form.

3.5. Implementation of regulations on medical equipment price declaration

The company has made a price declaration at the Hanoi Department of Industry and Trade regarding the purchase

Selling “Software for storing and transmitting medical images”

3.6. Implementation of medical equipment labeling

The company has not yet imported or traded medical equipment, so it has not yet carried out equipment labeling
medical

3.7. Implementation of medical equipment advertising

At the time of inspection, the Company had not yet carried out advertising

II. COMMENTS OF THE INSPECTION TEAM

- ASIA ACTUAL VIETNAM COMPANY LIMITED carries out production, import and trading

medical equipment business;

- Recommend that the Company review when implementing appropriate procedures for declaring medical equipment of type A and B

with regulations according to Official Dispatch No. 2098/BYT-TB-CT dated April 12, 2023 of the Ministry of Health.

- The company does not import or trade medical equipment containing drugs and money matter.

- According to the report, the company has had no post-sale incidents or number recalls circulation and medical products of competent authorities;

- The company conducting business in medical equipment has a business location at the correct registered address.⁴

- It is recommended that the company continue to research and maintain the correct and complete implementation of regulations

Laws on business, import, labeling and advertising of medical devices.

- Request ASIA ACTUAL VIETNAM COMPANY LIMITED to present original documents of

products in the order numbers 2, 5, 12, 17, 26, 37, 39 57, 77, 89 in the LIST OF FORM PUBLISHED ON THE ONLINE PUBLIC SERVICE SYSTEM PAGE MEDICAL EQUIPMENT MANAGEMENT OF ASIA ACTUAL VIETNAM COMPANY LIMITED at

Department of Health Inspectorate at 2:00 p.m. on August 28, 2024, address: 59 Nguyen Thi Minh Khai,

Ben Thanh Ward, District 1.

III. FACILITIES' OPINIONS ARE CHECKED

.....
...

.....
...

The minutes are made in 02 copies; have the same content and legal value; basis okay

The inspection team keeps 01 copy, the inspection team 01 copy, which is read back to the inspected facility and others

Relevant members listen and acknowledge that the above information is correct. Report ends at 10:30 the same day.

In addition to photocopied documents provided by the company, the Inspection Team did not keep any documents

anything else belonging to the company./.

**Facility being inspected Person making the record Representative of the
Inspection Team**

Mai Thi Le Trinh

Le Tuan Anh

Tran Thi Dieu Ai

Ha The Binh