

Ho Chi Minh City, April 17, 2024

PLAN

Check compliance with legal regulations related to production , import and export, purchase, sale, management and use of medical equipment in Ho Chi Minh City in 2024

Pursuant to Decree No. 117/2020/ND-CP dated September 28, 2020 of the Government stipulating penalties for administrative violations in the health sector;

Pursuant to Decree 124/2021/ND-CP dated December 28, 2021 of the Government amending and supplementing a number of articles of Decree 115/2018/ND-CP dated September 4, 2018 of the Government regulating the handling of penalties for administrative violations of food safety and Decree No. 117/2020/ND-CP dated September 28, 2020 of the Government regulating penalties for administrative violations in the health sector;

Pursuant to Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on medical equipment management;

Pursuant to Decree No. 07/2023/ND-CP dated March 3, 2023 of the Government on amending and supplementing a number of articles of Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on medical equipment management;

Pursuant to Decree No. 96/2023/ND-CP dated December 30, 2023 of the Government detailing a number of articles of the Law on Medical Examination and Treatment;

Pursuant to Decision No. 7115/QĐ-BYT dated December 1, 2016 of the Minister of Health promulgating the medical equipment inspection process;

Pursuant to Plan No. 65/KH-SYT dated January 3, 2024 of the City Department of Health on medical inspection in 2024;

Ho Chi Minh City Department of Health develops a Plan to inspect compliance with legal regulations related to production, import, export, purchase, sale, management and use of medical equipment in the area. Ho Chi Minh City in 2024 is as follows:

I. PURPOSE – REQUIREMENTS

1. Purpose:

- Strengthen the efficiency of state management of medical equipment;
- Propagate and disseminate legal documents related to medical equipment for establishments that produce, import, export, purchase, sell, manage and use medical equipment in Ho Chi Minh City. ;
- Ensure facilities operating in the field of medical equipment comply with legal regulations;

- Timely detect and correct violations and handle them strictly according to regulations (if any).

2. Requirements:

- Inspection work must be carried out in accordance with the provisions of law;
- Members participating in the medical equipment inspection team must be responsible for fully participating and coordinating according to inspection tasks;
- Guide, propagate and disseminate legal documents on medical devices;
- Check the implementation of legal regulations on the field of medical equipment at facilities:
 - + Production of medical equipment.
 - + Import and export of medical equipment.
 - + Buying and selling medical equipment of types B, C, D.
 - + Management and use of medical equipment at medical examination and treatment facilities.
- Focus on inspecting and taking samples to test medical equipment when there are signs of quality violations during the production and circulation process.

II. SUBJECTS AND CONTENTS OF INSPECTION

1. Inspection objects:

- Organizations and individuals producing, announcing applicable standards, importing and exporting, purchasing and selling medical equipment operating in Ho Chi Minh City.
- Hospitals, medical examination and treatment facilities and other units that manage and use medical equipment in medical examination and treatment.
- Facilities under the direction of competent State agencies; There are letters of feedback, complaints and denunciations; reflection from the media.

2. Inspection content:

Carry out inspection with the contents according to Decision No. 7115/QĐ-BYT dated December 1, 2016 of the Minister of Health on promulgating the medical equipment inspection process.

III. IMPLEMENTATION PLAN

1. Decision to establish an Inspection Team:

The Director of the Department of Health established an inspection team with members including: Inspector of the Department of Health; Department of Financial Planning; Department of Health Services Administration; Representatives of the District Health Department and Thu Duc city; Ho Chi Minh City Police representative (In case of complex unexpected inspections or under the direction of a competent state agency).

2. Assign and organize inspection

The Department of Health's inspection team will inspect facilities manufacturing, importing, exporting, purchasing, selling, managing and using medical equipment in Ho Chi Minh City according to the attached checklist.

- Inspection period: from May 1, 2024 to December 31, 2024.
- Legal basis for handling administrative violations: Legal regulations on production, import and export, purchase, sale, management and use of medical equipment and other relevant legal regulations.
- Handling administrative violations: In case an establishment commits administrative violations, the Chief Inspector of the Department shall issue a decision to sanction administrative violations if the violations fall within the authority of the Chief Inspector of the Department; In cases where a facility has many violations under the jurisdiction of many branches or the level of violations exceeds the authority of the Chief Inspector of the Department of Health, the Department Inspector will advise the Department Director to submit to the People's Committee. The city decides to impose penalties according to the level of violation.

3. Form of inspection:

In order for the inspection to be objective, the Inspection Team will conduct inspection in two forms:

- *Periodic inspection (notice in advance):*

For units according to the approved list attached with the plan of facilities expected to be inspected in 2024, there are no complaints, complaints or denunciations.

- *Unscheduled inspection:*

For other units related to feedback, complaints, and denunciations, there is direction of unexpected inspection from the Department of Health leadership or direction of a competent State agency.

4. Budget estimate:

The Inspectorate of the Department of Health estimates the operating budget for the Inspection Team from the revenue from sanctioning administrative violations.

IV. IMPLEMENTATION STEPS AND IMPLEMENTATION TIMELINE

Step 1: Plan and organize the implementation of the inspection plan to relevant units.

Step 2: Estimate personnel and advise the Director of the Department of Health to issue the Decision to establish an inspection team.

Step 3: Meet the Inspection Team to implement the plan, hand over the Decision to establish the Inspection Team and distribute documents and information related to the inspection of medical equipment to members of the Inspection Team, and distribute work, organize implementation, and schedule inspections.

Step 4: Conduct inspection and handle violations of violating facilities (If any).

Step 5: Department of Health Inspectors compile statistics, synthesize inspection results and report quarterly inspection results and summary reports according to regulations.

Above is the Plan to inspect the production, import, export, purchase, sale, management and use of medical equipment in Ho Chi Minh City. It is recommended that functional departments under the Department of Health coordinate with the Inspectorate of the Department of Health to inspect the good implementation of the proposed Plan./.

Receiving place:

- Inspectorate of the Ministry of Health;
- Department of Infrastructure and Medical Equipment - MOH;
- City Inspector;
- City Police; - Board of Directors of the Department;
- Health Services Management Department (for coordination);
- Planning and Finance Department (for coordination);
- Q/H Health Department (for coordination);
- City Health Department. Thu Duc (for coordination);
- Saved: VT, Ttra
(LTA-HVH-06b)

**KT. MANAGER
VICE PRESIDENT**

Nguyen Hoai Nam

**LIST OF FACILITIES THAT PRODUCTION, IMPORT, EXPORT, BUY AND SELL AND MANAGE AND USE MEDICAL EQUIPMENT
INSPECTION**

ACCORDING TO THE 2024 PLAN

(Attachment to Plan No. 3297/KH-SYT dated April 17, 2024)

Status	Business Name	Business field	Address			
			Number	Road	Ward	District/District City
1	Hue Chi Company Limited	Manufacturing, trading, importing and exporting medical equipment	17	Einstein	Binh Tho	Thu Duc
2	Chuong Nhan Trading Service Company Limited	Manufacturing, trading, importing and exporting medical equipment	16	Quach Van Tuan	12	Tan Binh
3	Thallo Distribution Joint Stock Company	Manufacturing, trading, importing and exporting medical equipment	104	Hoang Dieu	12	4
4	NT Solutions LLC	Manufacturing, trading, importing and exporting medical equipment	35	A4	12	Tan Binh
5	Minh Nhi Medical Equipment Company Limited	Manufacturing, trading, importing and exporting medical equipment	487-489	Mrs. Hat	8	10
6	Alphachem Trading and Services Company Limited	Manufacturing, trading, importing and exporting medical equipment	457/24C	August Revolution	13	10

7	BMS Medical Equipment Company Limited	Manufacturing, trading, importing and exporting medical equipment	1A42	Hamlet 1	Pham Van Hai	Binh Chanh
8	Bach Viet Medical Equipment Joint Stock Company	Manufacturing, trading, importing and exporting medical equipment	456-458	Hai Ba Trung	Tan Dinh	1
9	MK Skincare Import Export Production Trading Service Company Limited	Manufacturing, trading, importing and exporting medical equipment	K31, Thoi An Residential Area	Le Thi Rieng	Thoi An	12
10	EMC Medical Equipment Company Limited	Manufacturing, trading, importing and exporting medical equipment	162/3	Dien Bien Phu	17	Binh Thanh
11	Hoang Phuc Anh Medical Equipment Company Limited	Manufacturing, trading, importing and exporting medical equipment	277	Tran Binh Trong	4	5
12	Huy Hoang Medical Equipment and Supplies Company Limited	Manufacturing, trading, importing and exporting medical equipment	102/10/3	Nguyen Tu Gian	12	Go Vap
13	Hung Phat Medical Equipment Company Limited	Manufacturing, trading, importing and exporting medical equipment	D7/9	National Highway 1A	Quarter 4, Tan Tuc Town	Binh Chanh
14	Lavicom Company Limited	Manufacturing, trading, importing and exporting medical equipment	311	Le Hong Phong	2	10
15	Ho Chi Minh City Medical Technical Equipment	Manufacturing, trading, importing and exporting	252-254	Cong Quynh	Pham Ngu	1

	Joint Stock Company	medical equipment			Lao	
16	My Van Development Company Limited	Manufacturing, trading, importing and exporting medical equipment	280A17	Luong Dinh Cua	An Phu	Thu Duc
17	Ngoc Nguyen Technical Services Trading Company Limited	Manufacturing, trading, importing and exporting medical equipment	212/32	Strategy	Binh Tri Dong	Binh Tan
18	Nhat Ha Medical Equipment Company Limited	Manufacturing, trading, importing and exporting medical equipment	495-497	Pham Van Bach	15	Tan Binh
19	Thuy An Biotechnology Joint Stock Company	Manufacturing, trading, importing and exporting medical equipment	253/14	Ha Huy Giap	Thanh Loc	12
20	Song Bao Medical Company Limited	Manufacturing, trading, importing and exporting medical equipment	67	violating right will	12	5
21	Tam An Medical Equipment Company Limited	Manufacturing, trading, importing and exporting medical equipment	338/27	Nguyen Dinh Chieu	4	3
22	TBR Technology Joint Stock Company	Manufacturing, trading, importing and exporting medical equipment	51	26	Binh Tri Dong B	Binh Tan
23	Tin Uy Medical Equipment Engineering Company Limited	Manufacturing, trading, importing and exporting medical equipment	47/71	Nguyen Huu Tien	Tay Thanh	Tan Phu
24	Truong Duong Trading Investment Joint Stock	Manufacturing, trading,	160	Truong Cong	14	Tan Binh

	Company	importing and exporting medical equipment		Dinh		
25	Cpc1 Central Pharmaceutical Joint Stock Company	Manufacturing, trading, importing and exporting medical equipment	297/24A	Ly Thuong Kiet	15	11
26	K&A Medical Equipment Company Limited	Manufacturing, trading, importing and exporting medical equipment	114/44	Tam Chau	Tam Binh	Thu Duc
27	Asia Actual VietNam Company Limited	Manufacturing, trading, importing and exporting medical equipment	45/90	Binh Tien	7	6
28	PT Healthcare Services and Trading Joint Stock Company	Manufacturing, trading, importing and exporting medical equipment	78/1C	Binh Loi	13	Binh Thanh
29	Doan Gia Saigon Trading Company Limited	Manufacturing, trading, importing and exporting medical equipment	466/6	Le Van Sy	14	3
30	Nguyen Long Company Limited	Manufacturing, trading, importing and exporting medical equipment	1/22/26	Nguyen Van Sang	Tan Son Nhi	Tan Phu