MINISTRY OF HEALTH	**SOCIALIST REPUBLIC OF VIETNAM**
_____	**Independence - Freedom - Happiness**
No: 05/2022/TT-BYT	_____
	Hanoi, August 1, 2022

NOTICE _
Detailing the implementation of a number of articles of Decree No. 98/2021/ND-CP November 8, 2021 of the Government on the management of medical equipment

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Pursuant to Decree No. 75/2017/ND-CP dated June 20, 2017 of the Government defining the functions, tasks, powers and organizational structure of the Ministry of Health;

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

At the request of the Director of the Department of Medical Equipment and Construction;

The Minister of Health promulgates a Circular detailing the implementation of a number of articles of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021 on the management of medical equipment.

Article 1. Scope

1. This Circular details the implementation of a number of articles of the Government's Decree No. 98/2021/ND-CP dated November 8, 2021 on the management of medical equipment (hereinafter abbreviated as Decree No. No. 98/2021/ND-CP) including:

a) Classification of medical equipment specified in Clause 5, Article 5 of Decree No. 98/2021/ND-CP;

b) Supplementing the list of in vitro diagnostic medical equipment that is not subject to quality assessment by a competent Vietnamese agency specified at Point dd, Clause 3, Article 30 of Decree No. 98/2021/ND- CP;

c) The list of medical equipment of types B, C and D that can be bought and sold as normal goods specified in Clause 1, Article 42 of Decree No. 98/2021/ND-CP;

d) The list of medical equipment that must be inspected for safety and technical features specified in Clause 10, Article 70 of Decree No. 98/2021/ND-CP;

dd) The list of medical equipment for which import permits are granted is specified at Point d, Clause 2, Article 76 of Decree No. 98/2021/ND-CP.

2. Announce the expiration of a number of documents on management of medical equipment.

Article 2. Regulations on classification of medical equipment

1. Medical devices are classified according to one or a group to determine the level of risk and the level of circulation.

2. The classification of one or a group of medical equipment must be based on the classification rules for risk levels A, B, C , D (specifically specified in Appendix I issued together with the Circular). this).

3. The form of the result of classification of medical equipment is made according to Appendix II of this Circular.

Article 3. Supplementing the list of in vitro diagnostic medical equipment that is not subject to quality assessment by a competent Vietnamese authority specified at Point dd, Clause 3, Article 30 of Decree No. 98/2021/ND -CP

1. Has been granted a certificate of free sale (Certificate of Free Sale) by one of the following countries or organizations:

a) US Food and Drug Administration (FDA) - USA;

b) Therapeutic Goods Administration (TGA) - Australia c;

c) Health Canada (Health Canada);

d) Ministry of Health, Labor and Welfare of Japan (MHLW);

dd) Japan Pharmaceutical and Medical Device Agency (PMDA);

e) China's National Medical Products Administration (NMPA);

g) The Korean Ministry of Food and Drug Safety (Ministry of Food & Drug Safety - MFDS);

h) EU member countries grant them according to regulation 2017/746 issued on 5 April 2017 of the Council and the European Parliament on in vitro diagnostic medical devices (Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices).

2. Having been granted a free-sale registration number or a certificate of circulation registration, or licensed to import in a commercial form in Vietnam, except for cases where it has been revoked.

3. Not an in vitro reagent, calibrator, or control material.

Article 4. List of medical equipment of types B, C , D which can be bought and sold as ordinary goods according to the provisions of Clause 1, Article 42 of Decree No. 98/2021/ND-CP

1. Personal blood pressure monitor.

2. Blood oxygen saturation (SpO2) meter using a finger clip battery.

3. Children's nasal aspirator.

4. Electronic thermometer, infrared thermometer.

5. Medical equipment used to measure personal blood sugar: blood glucose meter, blood collection pen, test strip, blood collection needle, standard solution, control solution.

6. Nebulizer.

7. Personalized medical bandages and gauze.

8. Artificial tears are classified as medical devices.

9. Condoms.

10. Contraceptive film (does not contain drugs).

11. Vaginal lubricants are classified as medical devices.

12. Hot and cold packs using electricity.

13. Self-testing in vitro diagnostic medical equipment of class B.

14. In vitro diagnostic medical equipment for self-testing for HIV, SARS-CoV-2.

Article 5. List of medical equipment that must be inspected for safety and technical features as prescribed in Clause 10, Article 70 of Decree No. 98/2021/ND-CP

1. Ventilator.

2. Anesthesia machine with breathing apparatus.

3. Electric scalpel.

4. Newborn incubator.

5. Defibrillator.

6. Artificial kidney machine.

Article 6. List of medical equipment licensed for import to comply with the provisions of Point d, Clause 2, Article 76 of Decree No. 98/2021/ND-CP

1. X-ray imaging equipment.

2. Magnetic Resonance System.

3. Diagnostic ultrasound machine.

4. Diagnostic endoscopy system.

5. Cyclotron system.

6. Radioisotope diagnostic equipment (system PET, PET/CT, SPECT, SPECT/CT, device for measuring iodine concentration I^{130}, I^{131}).

7. Automatic refractometer, cornea.

8. Electrophysiological machine (Electrical machine, Electrocardiogram machine, Electromechanical machine).

9. Electroretinometer.

10. Osteoporosis meter.

11. Fundus tomography machine; Fundus fluoroscopy machine.

12. Ultrasound fetal heart rate monitor.

13. Respiratory function analyzer/meter.

14. Biochemistry analyzer; Electrolyte and blood gas analyzer.

15. Hematology analyzer; Blood group analyzer.

16. Coagulation meter; erythrocyte sedimentation rate meter.

17. Elisa test system.

18. Cell extractor.

19. Platelet aggregation and function analyzer.

20. Bacteria and virus identification machine.

21. Immunoassay machine.

22. In vitro reagents, calibrators, and control materials.

23. X-ray treatment equipment.

24. Laparoscopic surgery system.

25. Radiation therapy equipment (Cobalt machine for cancer treatment, Linear accelerator for cancer treatment, Gamma scalpel of all kinds, Brachytherapy equipment of all kinds).

26. Patient monitor.

27. Infusion pump; Electric injection pump.

28. Scalpel (high frequency electricity, laser, ultrasound).

29. Surgical microscope.

30. Prostate surgery equipment system.

31. Artificial heart-lung machine.

32. Positioning device in surgery.

33. Cryosurgery equipment.

34. Newborn incubators; Baby warmer.

35. Anesthesia/anesthesia machine with breathing apparatus.

36. Ventilator.

37. Defibrillator, pacemaker.

38. High pressure oxygen chamber.

39. Extracorporeal lithotripsy/endoscopic lithotripsy system.

40. System of high-intensity ultrasound equipment for tumor treatment.

41. Dialysis equipment.

42. Specialized ophthalmic surgical system (Excimer Laser, Phemtosecond Laser, Phaco, Vitreous cutter, Corneal flap cutter).

43. Eyeglasses, contact lenses (nearsightedness, farsightedness, astigmatism) and contact lens preservation solution.

44. Laser therapy machine used in ophthalmology.

45. Long-term implantation devices and materials (over 30 days) into the body.

46. Types of equipment and materials for intervention in the body of cardiology, cranial nerves.

Article 7. Effect

1. This Circular takes effect from August 1, 2022.

2. The contents detailing the implementation of a number of articles of Decree No. 98/2021/ND-CP in this Circular shall be applied from the effective date of Decree No. 98/2021/ND-CP.

3. Form No. 13.01, Form No. 13.02 specified in Appendix I and form specified in Appendix V of Circular No. 19/2021/TT-BYT dated November 16, 2021 of the Minister of Health providing for sample documents. The copy and report on implementation of Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on management of medical equipment shall cease to be effective from the effective date of this Circular.

4. The following documents cease to be effective from January 1, 2022:

a) Circular No. 39/2016/TT-BYT dated October 28, 2016 of the Minister of Health detailing the classification of medical equipment;

b) Circular No. 46/2017/TT-BYT dated December 15, 2017 of the Minister of Health detailing the implementation of a number of articles of Decree No. 36/2016/ND-CP dated May 15, 2016 of the Government on the management of medical equipment;

c) Circular No. 33/2020/TT-BYT dated December 31, 2020 of the Minister of Health providing for the list of medical equipment subject to safety inspection and technical features;

d) Clause 1, Article 1 of Circular No. 23/2021/TT-BYT dated December 9, 2021 of the Minister of Health amending and supplementing a number of legal documents promulgated by the Minister of Health.

Article 8. Implementation roadmap

1. For medical equipment specified in Clauses 1, 2 and 3, Article 5 This circular:

a) If purchased after December 31, 2022, the safety and technical features of the medical equipment must be inspected in accordance with the inspection process promulgated by the Minister of Health;

b) If purchased before January 1, 2023, the inspection must be completed by June 1, 2023 in accordance with the inspection process issued by the Minister of Health.

2. For medical equipment specified in Clauses 4, 5 and 6, Article 5 of this Circular:

a) If purchased after December 31, 2023, the safety and technical features of the medical equipment must be inspected in accordance with the inspection process promulgated by the Minister of Health;

b) If purchased before January 1, 2024, the inspection must be completed by June 1, 2024 in accordance with the inspection process promulgated by the Minister of Health.

Article 9. Implementation organization

Chief of the office; Chief Inspector of the Ministry; Director, Director, General Director of the Ministry of Health; Directors of Health Services of provinces and centrally run cities and relevant agencies, organizations and individuals are responsible for the implementation of this Circular.

In the course of implementation, if there are any difficulties or problems, agencies, organizations and individuals are requested to promptly report them to the Ministry of Health for consideration and settlement./.

Recipients:
- Social Committee of the National Assembly;
- Office of the Government (Department of KGVX, Official Gazette, e-portal portal) Government);
- Ministry of Justice (Department for Examination of Legal Documents);
- Ministries, ministerial-level agencies , Governmental agencies;
- Q. Minister of Health (for b/c);
- The Deputy Ministers of Health (to coordinate and direct);
- People's Committees of provinces and centrally run cities;
- Departments of Health of provinces and centrally run cities;
- Departments of Science and Technology of the provinces and cities directly under them Center;
- Vietnam Social Insurance;
- Units under the Ministry of Health; health care ministries and branches;
- Departments, Departments, General Department, Office of the Ministry, Inspectorate of the Ministry;
- Portal of the Ministry of Health;
- Save: VT, PC, TB-CT

KT. MINISTRY OF MINISTRY
Vice Minister _

Do Xuan Tuyen

Appendix I
CLASSIFICATION OF MEDICAL DEVICES
(Issued together with Circular No. 05 */2022/TT-B Y T dated August 1, 2022 of the Minister of Health)*
Section 1
RULES FOR CLASSIFICATION OF MEDICAL DEVICES
Part I
DEFINITIONS

In this rule, the following terms are construed as follows:

1. Active medical equipment means medical equipment operating on the principle of using and transforming electrical energy or other energy sources that are not sources of energy generated by the human body or the world. power. Medical devices used to transfer energy, substances or other elements from the active medical device to the human body without causing major changes to these elements are not defined as equipment. active medical device.

2. Active therapeutic medical device means a medical device that is used alone or in combination with other medical devices to support, modify, replace or restore functions or structures. biological structures for the purpose of treating or alleviating disease, injury or disability.

3. Active diagnostic medical equipment means medical equipment used alone or in combination with other medical devices, to provide information for detection, diagnosis, monitoring or to assist in the treatment of a physiological, medical condition, disease or birth defect.

4. Body holes are natural openings in the body, including the outer surface of the eyeball, or any permanent permanent artificial opening such as a tracheostomy or intubation hole.

5. The central circulatory system is the main blood vessels inside, including:

a) Pulmonary artery (Arteriae pulmonales)

b) ascending aorta

c) Coronary artery (Arteriae coro nariae)

d) Common carotid artery (Arteria carotis communis)

d) External carotid artery (Arteria carotis externa)

e) Internal carotid artery (Arteria carotis intema)

g) Cerebellar artery (Arteriae cerebrates)

h) The brachiocephalic artery (Truncus brachiocephalicus)

i) Thoracic aorta (Thoracica aorta)

k) Abdominal aorta (Abdominalis aorta)

l) Common iliac artery (Arteriae ilica communis)

m) Aorta descendens to the bifurcatio aortae

n) Aortic arch (Arcus aorta)

o) Cardiac vein (Venae cordis)

p) Pulmonary vein (Venae pulmonales)

q) Superior vena cava (Venae cava superior)

r) inferior vena cava

6. The central nervous system consists of the brain, meninges and spinal cord.

7. Continuous use of a medical device means the use of a medical device that does not include any temporary interruption in the course of or any interruption in the use of such medical device in order to for the purpose of cleaning or disinfecting or for consecutive use of a medical device by immediately replacing it with a device of the same type, as directed by the product owner.

8. Temporary use is continuous use for less than 60 minutes.

9. Short-term use is continuous use for a period of 60 minutes to 30 days.

10. Long-term use is continuous use for more than 30 days.

11. Immediate danger is a situation where the patient's life or vital physiological function is in danger if immediate precautions are not taken.

12. Intrusive medical device means a medical device that partially or completely penetrates inside the body through a hole in the body or through the surface of the body, including: implanted medical equipment transplants, medical devices that enter the body through surgery, medical devices that penetrate the body through natural openings, and medical devices that penetrate through the body surface.

13. Implantable medical device means a medical device that is implanted, surgically implanted into the human body or to replace part of the epithelial or ocular surface for the purpose of maintaining function. of organs after surgery, transplantation, including medical devices used to insert a part into the body through surgical intervention for the purpose of maintaining the function of the organ after surgery, transplant within at least 30 days.

14. Surgically invasive medical device is an invasive medical device that is introduced into the body through the surface of the body with surgical assistance, including invasive devices. body does not pass through natural holes.

15. Self-testing in vitro diagnostic medical equipment is an in vitro diagnostic medical device that is designated by its owner for use by persons who have not been trained in the relevant field.

16. On-site test means a test performed outside the laboratory of a medical examination and treatment establishment or a professional center, which can be performed at the patient's bedside or at the patient's living place.

17. Reagents are chemical, biological, immunological substances, solutions or preparations designated by the owner to be used as in vitro diagnostic medical equipment.

18. Sample container is an in vitro diagnostic medical device, vacuum type or not, designated by the owner to only be used to contain samples of human origin.

19. A communicable agent is an agent capable of being transmitted to humans, such as a contagious or infectious disease.

20. Transmission is the transmission of disease to humans.

21. A life-supporting or life-sustaining device is a medical device that is necessary or produces information necessary for the restoration and maintenance of a bodily function that is vital to the maintenance of life. of human.

Part II
CLASSIFICATION RULE C FOR MEDICAL DEVICES NOT DIAGNOSTIC MEDICAL DEVICE I N VITRO

A. CLASSIFICATION RULES FOR NON-invasive MEDICAL DEVICES

Rule 1. Classification for medical devices in contact with damaged skin

1. All non-invasive medical devices that come into contact with skin wounds of category A if used as a mechanical barrier, with only the function of condensing or absorbing fluids for the purpose of initial wound healing.

2. Non-invasive medical devices used primarily with wounds that penetrate the dermis, including medical devices used primarily to control the wound microenvironment of type B.

3. Non-invasive medical devices used primarily for wounds that penetrate the dermis and are only otherwise healed by means of Class C.

Rule 2. Classification for non-invasive medical devices used for transmission or storage

All non-invasive medical devices intended for the transmission or storage of bodily fluids, tissues, liquids or gases with the ultimate purpose of infusion, Drinking or putting into the body is classified as Class A if it does not fall into the following cases:

1. Medical equipment that can be connected to active medical equipment of class B or higher of

class B.

2. Medical devices used for blood transfusion, storage or infusion of other body fluids or preservation of organs, parts of organs or body tissues are of class B.

3. Blood bag of type C.

Rule 3. Classification for non-invasive medical devices with bio-chemical conversion function

Non-invasive medical devices used to change the chemical or biological composition of blood, body fluids or other fluids for infusion are classified as Class C. Unless the treatment includes filtration, centrifugation, or gas or heat exchange, this is class B.

Rule 4. Classification for other non-invasive medical devices

All other non-invasive medical devices are in Class A.

B. CLASSIFICATION RULES FOR INTRODUCTION MEDICAL DEVICES

Rule 5. Classification of non-surgical body orifice invasive medical devices

1. Medical devices that enter through the body's openings without surgery, must not be used to connect with active medical devices or only connect with medical devices of this type. A is in Class A if the medical devices are for temporary use. In the case of medical devices of this type intended for use on body surfaces, eyeballs or with mucosal absorptive capacity are Class B.

2. Medical devices that enter through the body's openings without surgery, must not be used to connect with active medical devices or only connect with medical devices of this type. A is in category B if the medical devices are intended for short-term use. Where this medical device is used in the body area from the oral cavity to the pharynx, from the cochlea to the tympanic membrane or in the nasal cavity, it is classified in class A.

3. Medical devices that enter through the openings of the body without surgery, must not be used to connect with active medical devices or only connect with medical devices of this type. A is in category C if these medical devices are used for a long time. In the case of this medical device used in the body area from the oral cavity to the pharynx, from the cochlea to the eardrum or in the nasal cavity and is not able to be absorbed by the mucosa is classified as class B.

4. All body orifice invasive medical devices (except surgical entry) intended to be connected to an active medical device of class B or higher are classified in type B.

Rule 6. Classification of surgically invasive medical devices for temporary use

All surgically invasive medical devices for temporary use are in Class B, if not in the following cases:

1. Medical devices are reusable surgical instruments of class A.

2. Medical devices used to provide energy in the form of ionizing radiation are class C.

3. Medical devices intended to produce biological effects or to be completely or largely absorbed are in Class C.

4. Medical devices intended to deliver medicinal products into the body by means of a delivery system that are potentially hazardous when applied are classified as Class C.

5. Medical devices specifically designated for use with direct central nervous system contact are in Class D.

6. Medical devices specifically indicated for the diagnosis, monitoring or repair of defects of the heart or of the central circulatory system by direct contact with these parts of the body are in Class D .

Rule 7. Classification of surgically invasive medical devices for short-term use

All invasive surgical medical devices for short-term use are classified as Class B if they do not fall into the following categories:

1. Medical devices used to deliver drug products are in category C.

2. Medical devices used to undergo chemical transformations in the human body (except in the case of devices placed in the teeth) are in class C.

3. Medical devices used to provide energy in the form of ionizing radiation are class C.

4. Medical devices used to produce a biological effect that are either completely or largely absorbed are in Class D.

5. Medical devices that come into direct contact with the central nervous system are classified as D.

6. Medical devices specifically indicated for the diagnosis, monitoring or repair of a defect of the heart or of the central circulatory system by direct contact with these parts of the body type D.

Rule 8. Classification of surgically invasive medical devices for long-term use and implantable medical devices

All surgically invasive medical devices for long-term use and implantable medical devices are classified as Class C if they do not fall into the following categories:

1. Medical devices used to place teeth are in class B.

2. Medical devices that, when used in direct contact with the heart, central circulatory system or central nervous system are classified as D.

3. Medical devices used to support or sustain life are classified as D.

4. Medical equipment that is also active medical equipment of class D.

5. Medical devices used with biological effects or completely or largely absorbed are in Class D.

6. Medical devices used to deliver drug products of category D.

7. When used, medical devices must undergo chemical transformations in the human body (except in the case of devices placed in the teeth) of class D.

8. Medical devices covered by this rule used for breast implants are Class D.

C. CLASSIFICATION RULES FOR ACTIVE MEDICAL DEVICES

Rule 9. Classification of active therapeutic medical devices

All active therapeutic medical devices intended for the delivery or exchange of energy are in Class B unless the following apply:

1. Active therapeutic medical devices that deliver or exchange energy to or from the human body in a manner that may pose a risk, including the emission of ionizing radiation taking into account the properties of, the density and site of application of the energy are classified as class C.

2. Active medical devices intended to control, monitor or directly affect the performance of class C active treatment medical devices are classified as C.

Rule 10. Classification of active medical devices for diagnostic use

1. Medical devices used to illuminate the patient's body with light in the visible or near-infrared spectrum region are classified as class A.

2. Active medical equipment used for diagnosis is class B if it falls into the following cases:

a) Used to provide energy absorbed into the human body (except for medical equipment specified in item a);

b) Used to capture the distribution of radioactive drugs in the human body;

c) Used to directly diagnose or monitor the physiological process of life.

3. Active medical equipment used for diagnosis shall be classified into class C if it falls into one of the following cases:

a) Used to monitor physiological parameters of life where changes in these parameters could lead to dangerous conditions for the patient, e.g. cardiac activity, respiration, activity action of the central nervous system.

b) Used for diagnostic purposes in clinical situations where the patient is in critical condition.

4. Active medical equipment used to emit ionizing radiation and used for radiological diagnosis and/or intervention, including medical devices that control, monitor Such medical devices or those

which directly affect their operation are classified in category C .

Rule 11. Classification of active medical devices with the function of providing and removing drugs, body fluids and other substances into or from the body

All medical devices covered by this rule are classified as Class B. Where these medical devices pose a risk to the patient due to the nature of the substances used, the part of the body involved. as well as the manner and route of delivery or removal of drugs and body fluids, these cases are classified in category C.

Rule 12. Classification of other active medical devices

All other active medical devices are classified as Class A.

OTHER CLASSIFICATION RULES

Rule 13. Classification of medical devices combined with pharmaceutical substances

Medical devices, which are combined with pharmaceutical substances for the purpose of assisting such medical devices to operate on or in the human body, are classified in category D.

Rule 14. Classification of medical devices of animal origin, bacteria

1. Medical equipment shall be classified into class D if it has components in one of the following cases:

a) Animal cells and tissues and their derivatives that cannot develop independently;

b) Cells, tissues and derivatives of bacterial or recombinant origin.

2. In the case of medical devices, which contain components from animal tissues or derivatives of animal tissues and cannot be developed independently if used only by contact with uninjured skin, they are classified as A.

Rule 15. Classification of sterilization and sterilization medical equipment

1. Medical equipment used to sterilize medical equipment is classified in class C.

2. Medical equipment used to disinfect medical equipment, whose sterilization is the final stage of the sterilization process, is classified in class C.

3. Medical equipment used to disinfect medical equipment where sterilization is carried out before sterilization is classified in class B.

4. Medical equipment used for sterilization where sterilization is carried out before final sterilization is classified as class B.

5. Medical devices specified for disinfecting, cleaning, soaking, rinsing or moisturizing contact lenses are classified in category C.

Rule 16. Classification of medical devices used to prevent pregnancy or prevent sexually transmitted diseases

1. Medical equipment used to prevent pregnancy or prevent sexually transmitted diseases is classified as C.

2. Where medical equipment used for contraception or prevention of sexually transmitted diseases is invasive medical equipment used for a long time or implanted, it is classified in category D.

Part III
CLASSIFICATION RULE C FOR IN VITRO DIAGNOSTIC MEDICAL EQUIPMENT

Rule 1. In vitro diagnostic medical devices used for any of the following purposes are classified in Class D

1. Used to detect the presence or exposure to an infectious agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability to perform a blood transfusion or transplant.

2. Used to detect the presence or exposure to an infectious agent that causes a life-threatening, often incurable disease with a high risk of transmission.

In vitro diagnostic medical device used for blood group determination or tissue classification to ensure immunocompatibility of blood, blood components, cells, tissues or organs for transfusion or transplants are classified as Class C , except for medical devices used to determine blood group ABO [A (ABO1), B (ABO2), AB (ABO3)], rhesus [RH1 (D)] blood groups, Rh2 (C), Rh3 (E), RH4 (c), RH5(e)], Kell system [Kell (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FYI (Fya)), FY2 (Fyb)] is classified as D.

Rule 3. In vitro diagnostic medical devices used for any of the following purposes are classified in class C

1. Detect presence or exposure to a sexually transmitted agent (eg sexually transmitted diseases, *Chlamydia trachomatis, Neisseria gonorrhoeae)*

2. Detect the presence of an infectious agent in cerebrospinal fluid or blood with limited transmissibility (eg, *Neisseria meningitidis* or *Cryptococcus neoformans).*

3. Detects the presence of an infectious agent that, when erroneously, poses a great risk of death or serious disability to the individual or fetus being tested (e.g. diagnostic test for CMV , *Chlamydia pneumoniae,* Methycillin-resistant Staphylococcus aureus).

4. Prenatal screening to determine immune status for infectious agents (eg, testing for immunity for Rubella or Toxoplasmosis).

5. Identification of an infectious disease or immunological condition where false test results may pose a near-term threat to the patient's life due to inappropriate treatment decisions (e.g. diagnostic testing). Enterovirus, CMV, and HSV diagnosis in transplant patients).

6. Selective screening of patients for appropriate management and therapy or for staging of disease or cancer diagnosis (eg personalized medicine).

In vitro diagnostic medical devices for which a treatment decision is usually made only after further evaluation and in vitro diagnostic medical devices used for monitoring will fall under category B according to the rule 6 – Part III.

7. Genetic testing in humans (eg, Huntington's disease, cystic fibrosis).

8. Monitor the concentration of drugs, substances or biological components where false test results can lead to immediate risk to the patient's life due to inappropriate treatment decisions (eg, cardiovascular markers, cyclosporin, clotting time tests).

9. Monitoring and treatment of patients with life-threatening infectious diseases (eg HCV viral load, HIV viral load and HIV, HCV genotype and genotype determination).

10. Screening for congenital disorders in the fetus (eg spina bifida or Down syndrome).

Rule 4

1. Self-testing in vitro diagnostic medical equipment is classified in category C. In case the test results of an in vitro diagnostic medical device do not serve a treatment decision or are only valid for reference and it is necessary to carry out appropriate additional tests at the laboratory, this equipment belongs to the following categories: type B.

2. In vitro diagnostic medical equipment used for on-site testing of blood gas and blood glucose parameters is class C. Other in vitro diagnostic medical devices are classified according to the respective classification rules.

Rule 5. In vitro diagnostic medical devices are classified in class A if they fall into one of the following cases:

1. Other products that participate in or support the performance of the test specified by the owner for the specific test-related in vitro diagnostic procedures.

2. Medical device designated by the owner for use in in vitro diagnostic procedures.

3. Sample container.

Rule 6. In vitro diagnostic medical devices that do not fall under rules 1 to 5 are classified in class B.

Rule 7. In vitro diagnostic medical devices are control materials with no quantitative or

qualitative value assigned to Class B.

Section 2
GROUP RULES FOR REGISTRATION OF NUMBER RANKING NUMBERS MEDICAL EQUIPMENT

Medical equipment can be classified according to a single medical device or a group of medical equipment as follows:

a) Family of medical equipment (hereinafter referred to as family);

b) In vitro diagnostic medical equipment set (hereinafter referred to as IVD kit);

c) The medical equipment system (hereinafter referred to as the system);

d) Cluster of in vitro diagnostic medical equipment (hereinafter referred to as IVD cluster);

dd) Other sets of medical equipment (hereinafter referred to as sets).

1. Principle of classification by single medical equipment

A medical device is classified under a single medical device if the medical device has been identified by the owner, a specific use, and is supplied as a separate package or as a medical device. that medical device does not meet the criteria for classification by medical device family, IVD set, medical device system, IVD medical device cluster or other set of medical equipment.

2. They have medical equipment - family

The medical device family is a collection of medical devices, each of which has the following information in common:

- Same product owner;
- Same type of risk classification;
- Have the same purpose of use;
- Have the same design and manufacturing process;
- There are changes within the allowable variations according to the list in Table 1.

Table 1. List of allowed variants in a medical device by family

Specific products	Permissible Variations
Dental implant post	Holder (e.g. cement or screws)
Active implant devices	Can be used with or without magnetic resonance equipment
Antibiotic Substance (IVD) Test	Concentration
Biopsy pliers	Fixed or non-fixed form
Blood bag	(i) Anticoagulants with the same composition but different concentrations (ii) Additives (Different composition and different concentration)
The catheter	(i) Number of lumens in the catheter (ii) Material of catheter: PVC (polyvinylchloride), PU (polyurethane), nylon and silicone (iii) Curvature (iv) Lubricating coatings

Condom	(i) Texture (ii) Smell
Lens	(i) Diop (ii) UV protection (iii) Color coating (iv) Color (v) Time of use (daytime wear or extended wear) (vi) Glass change time (daily, weekly or monthly)
Defibrillator	Automatic or semi-automatic
Brace	Material of braces
Dental handpiece	(i) Rotation speed (ii) Material of handpiece
Skin fillers	Same composition but different concentration/density
Diagnostic imaging system using ionizing radiation	(i) Number of slices (ii) Digital or analog (routine) (iii) Two planes or one plane (iv) Use flat receiver or Cassette (v) Collection ring size (for PET)
Electrophysiological probe catheter	(i) Distance between electrodes (ii) Number of electrodes
Gloves	Powder or not?
Camera Gamma	Number of receivers
Conductor	With or without inert coating material
Orthopedic/dental implants	(i) Fixed with cement or not (ii) Belt ring
Artificial vitreous _	(i) Single or multifocal (ii) Multiple pieces or single pieces (iii) Spherical or aspherical
Transplant supplement generator	Number of chambers of the heart (cardiovascular)
IV . Catheter	(i) Having an injection room (ii) Have a safe wing
Rapid test IVD	combination formats : tray, stick, pen, tube, stick, card
Urine test strips in test tubes	Test with a combination of parameters

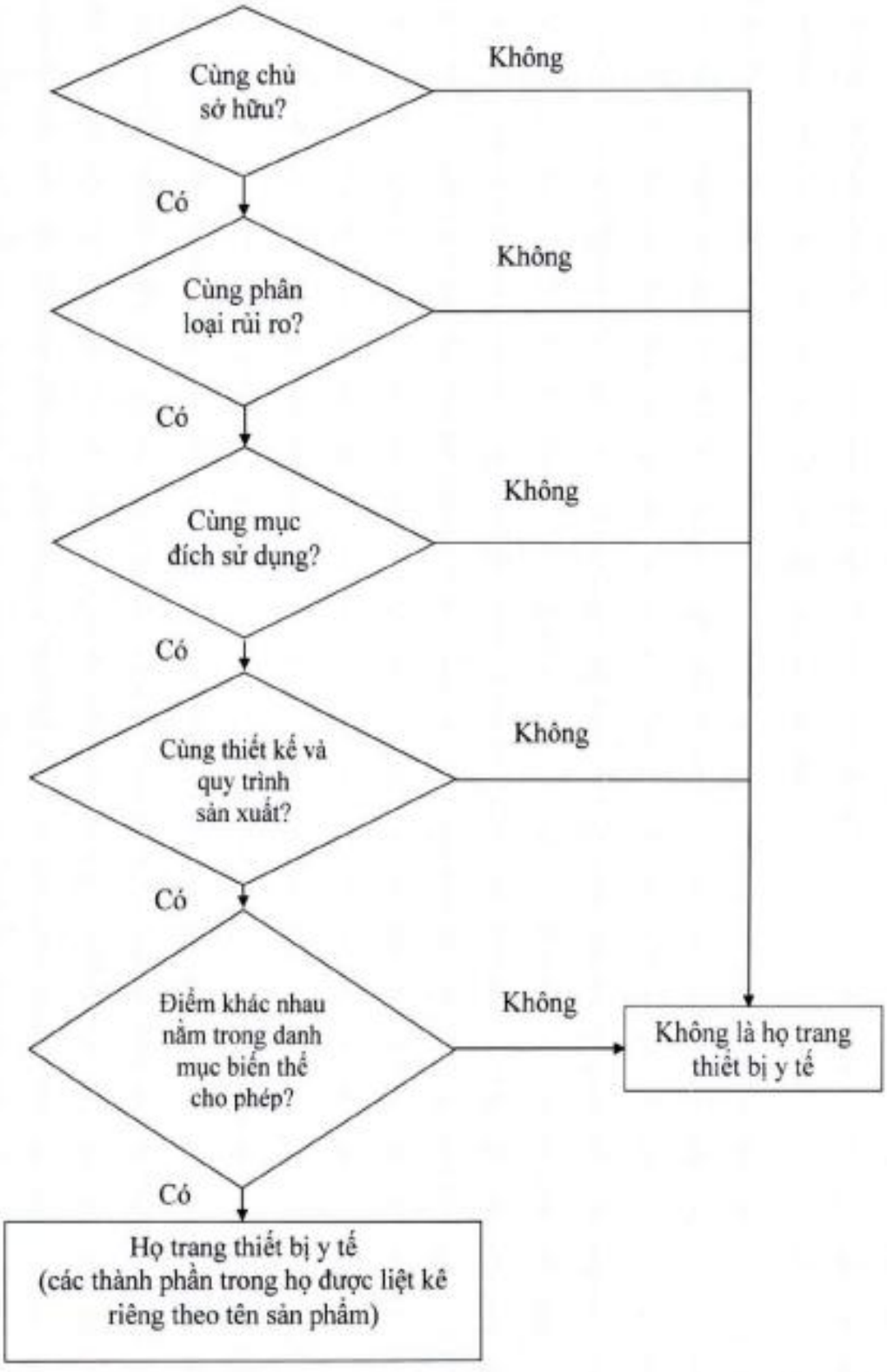
Polymer products	With or without plasticizer (e.g. diethylhexyl phthalate)
Support frame (stent)	(i) Stent delivery system, placed through the wire or placed through the endoscope (ii) Flap (surgery for graft) or outer tube
Thread	(i) Number of yarns (ii) Gauze (iii) Round (iv) Dyeing
Sewing thread tool	Design of jaws, handles and needles
Tracheal tube (endotracheal tube, tracheostomy tube)	With or without shadow
Dressing	Various forms (e.g. liquid, cream, gel, coating on pads...)
X-ray receiver	X-ray emitting material (in the photoluminescent bulb)

List of other generic variations allowed in a medical device by Family:

Coatings are for lubrication purposes only
Color
Diameter, length, width, size
Concentrations with the same indication and mechanism (same composition, different amounts of constitutive elements)
Size design differences due to pediatric versus adult use (These differences are due to differences in patient groups allowed, e.g. volume and length)
Flexibility
Grip force
Radioactivity level of isotope
Memory storage
Sterilization method (to achieve the same aseptic result)
Printability
Radiation shielding
Shape, size, volume

Viscosity (The change in viscosity is merely due to a change in the concentration of the constituent)
Hanging form (e.g. ceiling, wall or stand)
Sterile state (sterilized, non-sterile)

Diagram of grouping medical equipment by family



3. In vitro diagnostic medical equipment kit

An IVD Kit is a collection of in vitro diagnostic medical devices consisting of reagents or products that share the following information:

- Supplied from the same product owner;

- Used in conjunction with each other to accomplish a particular use;

- Supplied under the name IVD kit or on the label, the instructions for use of each reagent or product specifying the ingredient to be used with the IVD kit;

- Compatible when used as an IVD kit.

An IVD kit does not include equipment such as the analyzer needed to perform the test, an in vitro diagnostic medical equipment system may include IVD kits and equipment (e.g. Tester is set up). design for use with the test kit).

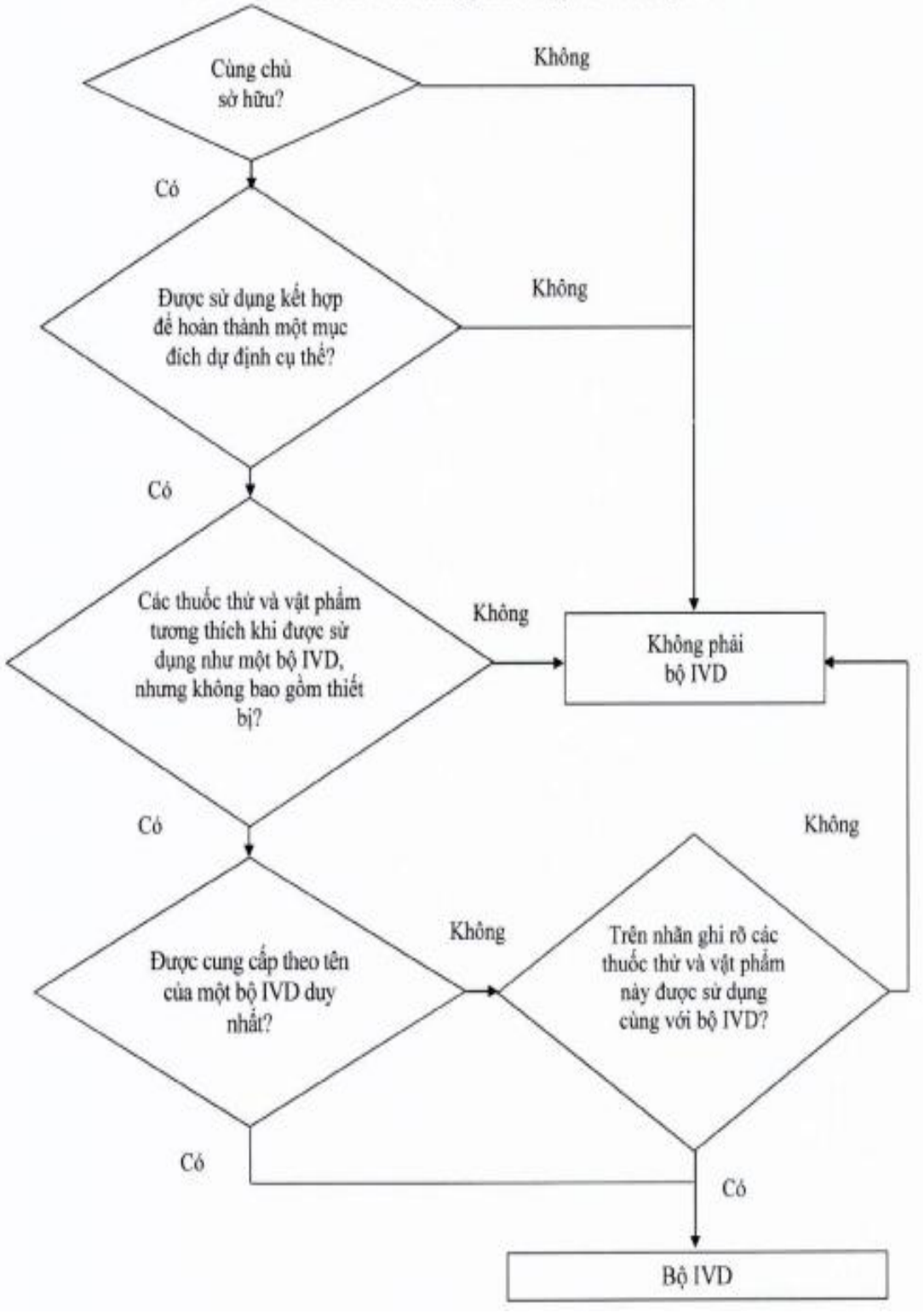
Each reagent or product in the IVD kit may be supplied separately for the replacement IVD kit. If reagents or products in an IVD kit are provided for use with multiple other IVD sets, those reagents or products must be registered with each of the different IVD sets or may be registered individually.

Reagents or products supplied by different owners can be grouped into the same IVD kit if the registrar can provide all the information required by this reagent and product such as authorization. registration authorization from the owner and data demonstrating the performance of these reagents when used in an IVD kit.

For example:

An Enzyme Immunoassay Kit (ELISA) for Human Immunodeficiency Virus (HIV) may contain controls, calibrators, and wash buffers. All these reagents and items are used together to detect HIV and so can be an IVD kit. These reagents and items may be supplied separately to replace the IVD kit.

Sơ đồ phân nhóm các trang thiết bị y tế theo bộ IVD



4. System

A medical equipment system consists of a number of medical devices and accessories or accessories combined together into a system, the components of which meet the following requirements:

- From one owner;

- Intended to be used in combination to achieve a common use;

- Compatible when used as a system;

- The components that make up a system have their own names. Where the system does not have a specific name, each component of the system shall be indicated on the label, instruction manual or technical document specifying the components to be used in conjunction with the system. together into a system.

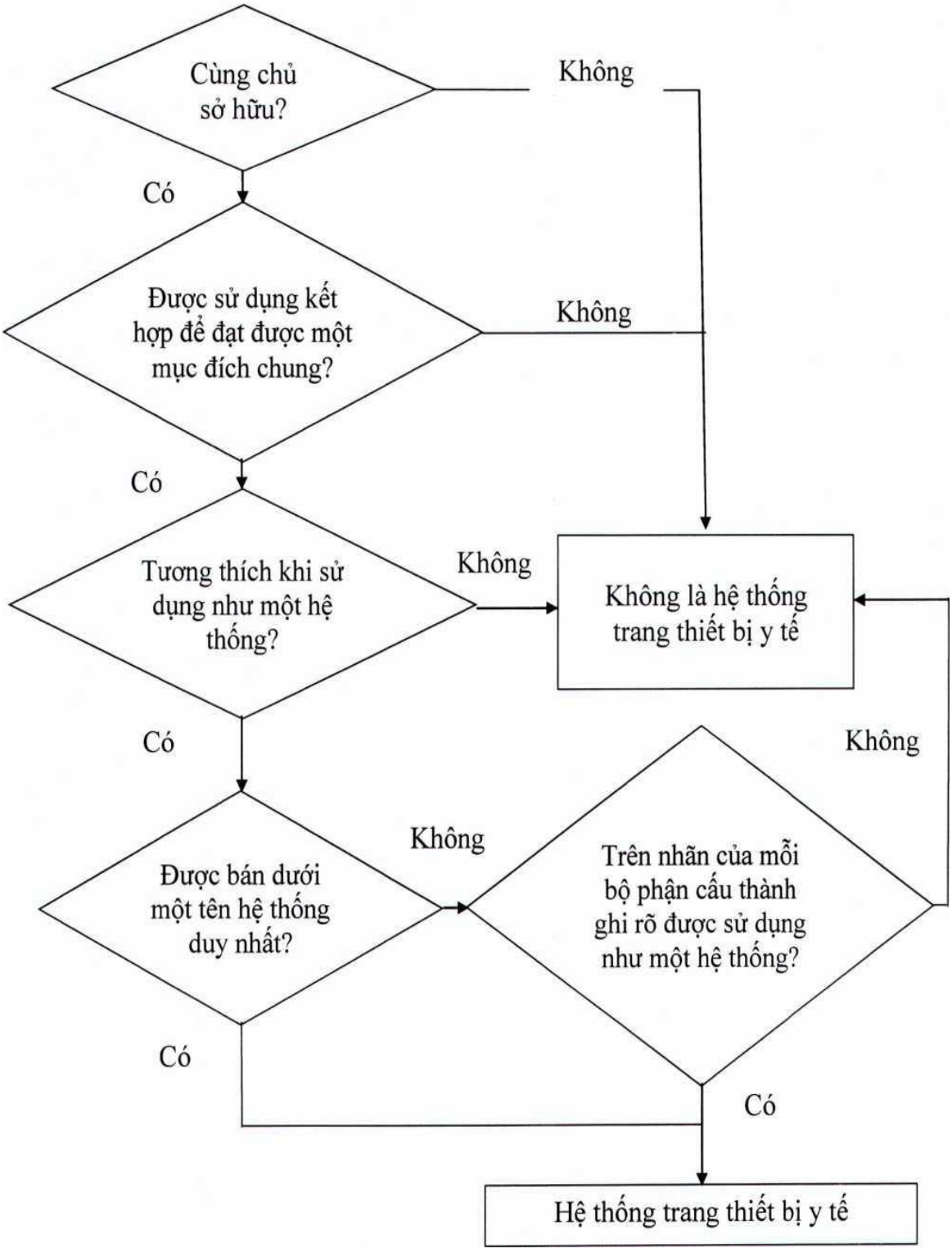
Equipment that is part of a system shall be provided for use with that system only. Where a device can be provided for use on more than one system, the device must be registered with each system separately or may be registered individually.

The owner of the system can incorporate devices and accessories from other owners that become part of the system to achieve the intended use of the system.

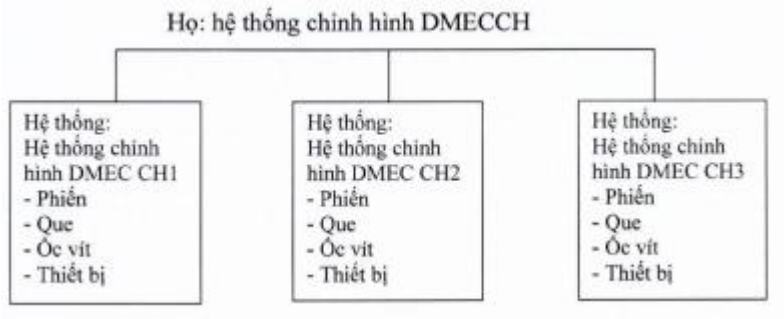
For example:

Owner A's patient monitoring system is intended for use with Owner B's vital signs sensors and probes. These accessories are used in combination to achieve one purpose. Standard general use by Owner A, and can be registered with the patient monitoring system in a single file.

Sơ đồ phân nhóm các trang thiết bị y tế theo hệ thống



Example of grouping multiple systems into a family:



Note: Key components such as implants, plates, and screws in systems are allowed variations. Variations in the lengths of implant screws are also considered permissible variations.

- *A hip replacement system* consisting of femur and acetabulum units can be registered as a system. These parts must be used in combination to achieve the common purpose of total hip replacement, parts sizes may vary.

- *An electrosurgery machine and accessories* including clamps, electrodes, electrode holder, main lead, combination plug, when used together for a common use, may be registered as one system.

One set of catheterization kits including knife , syringe, needle, surgical gloves, gauze, net and wash solution, has been evaluated for compatibility and assembled by one owner under a unique name to used in combination in surgical catheterization procedures, can be grouped into a system.

- *Automated sphygmomanometers* with optional features such as memory and the ability to print data with various models can be considered as a family of systems.

5. IVD diagnostic medical equipment cluster (IVD cluster)

The IVD cluster includes several reagents and products for in vitro diagnostics with the same information:

- Supplied from the same owner;

- Have the same risk classification (class A or B);

- Belongs to the same cluster of IVDs and a common test method listed in Table 2.

An IVD cluster may include analyzers designed for use with reagents in an IVD cluster.

Table 2. List of common test methods and cluster types IVD

STT	Method	Cluster type (closed list)	Example of analyte
first	Biochemical	Enzymes	(i) Acid Phosphatase (ii) Alpha-Amylase (iii) Creatine Kinase (iv) Gamma-Glutamyl Transferase (v) Lactate Dehydrogenase (vi) Lipase
2		Substrates	(i) Albumin (ii) Bilirubin (iii) Urea/Blood Urea Nitrogen (iv) Cholesterol (v) Creatinine (vi) Glucose

3		Electrolyte Reagents	(i) Ammonia (ii) Bicarbonate (iii) Calcium (iv) Chloride (v) Magnesium (vi) Phosphate Inorganic/Phosphorus
4		Electrolyte Electrolyte	(i) Ammonia electrode (ii) Carbon Dioxide (Bicarbonate) Electrode (iii) Calcium electrode (iv) Chloride electrode (v) Magnesium Electrode (vi) Potassium Electrode
5		Substrate Electrode/Biosensor	(i) Creatinine electrode (ii) Glucose Electrode (iii) Glycated Hemoglobin . Electrode (iv) Lactate electrode (v) Urea . electrode (vi) Bilirubin . electrode
6	Free	Immunoglobulins (no IgE)	(i) Immunoglobulin A (ii) Immune Globulin (ii) G immune globulin (iv) Immune Globulin US (v) Immunofixation Test Kit
7		Additional Ingredients	(i) Additional Ingredients C1q (ii) C1 . Inactivator Supplement Ingredients (iii) Additional Ingredients C3/C3c (iv) Supplements for Bb (v) Additional Ingredients C4 (vi) Additional Ingredients C5a
8		Transport Proteins	(i) Albumin (ii) Ceruloplasmin (iii) Haptoglobin (iv) Hemopixin (v) Lactoferrin (vi) Pre-albumin/Transthyretin
9		Lipoproteins	(i) Apolipoprotein AI (ii) Apolipoprotein A II (iii) Apolipoprotein B (iv) Apolipoprotein E Sub-typing (v) Lipoproteins (a)
ten		Other Specific Proteins	(i) a1-Acid Glycoprotein (ii) a1-Antitrypsin (iii) a1-Microglobulin (iv) Fibronectin (v) Immuno Reactive Trypsin

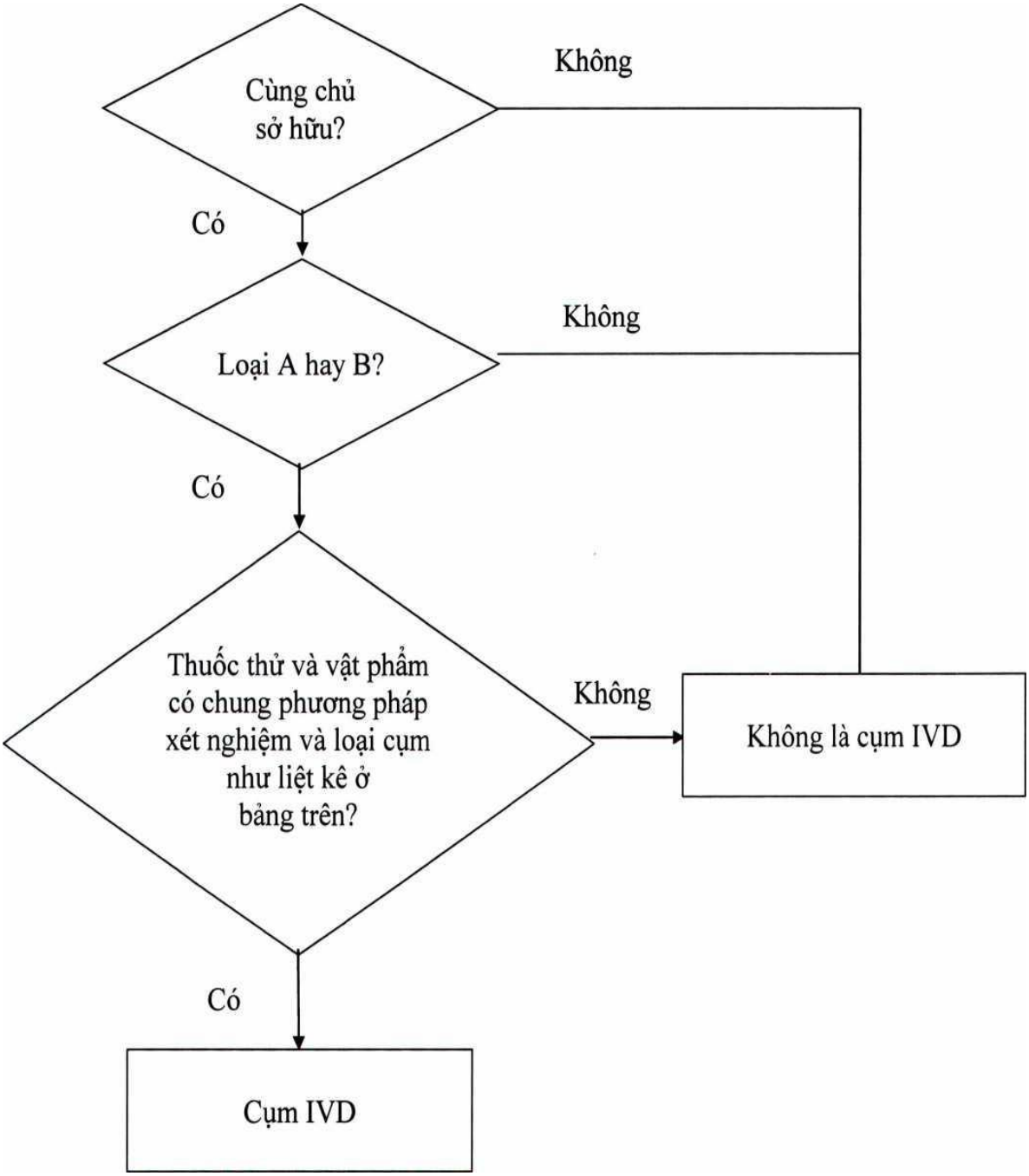
11		Allergy	(i) Immunoglobulin E - Overall (ii) Immunoglobulin E - Screening (iii) Immunoglobulin E - Specific, one trial/one result (iv) IgA .-specific allergens (v) IgG .-specific allergen
twelfth		Cancer markers	(i) GI Imprint CA242 (ii) p53
13		Thyroid function markers	(i) Free Triiodothyronine (ii) Free Thyroxine (iii) Thyroid Stimulating Hormone (iv) T - Uptake (v) Thyroglobulin (vi) Neonatal Thyroxine
14		Fertility / Pregnancy Hormones / Protein	(i) Androstenedione (ii) Estradiol (iii) Prolactin (iv) Placental Lactogen in Human (v) Estriol
15		Diabetes test (Hormone)	(i) C-Peptide (iii) Glucagon (iii) Insulin (iv) Glycosylated/Glycated Haemoglobin (v) Islet Cell Ab (vi) Proinsulin
16		Renal metabolism test	(i) Aldosterone (ii) Angiotensin I / II (iii) Angiotensin-converting enzyme (iv) Cortisol (v) Renine
17		Bone and mineral metabolism test	(i) Alkaline Phosphatase in bones (ii) Calcitonin (iii) Cross-linked C-Telopeptides (iv) Cross-linked N-Telopeptides (v) Cyclic Adenosine Monophosphate (vi) Hydroxyproline
18		Endocrine hormones and Peptides	(i) Adrenocorticotropic Hormone (ii) Human Growth Hormone (iii) Insulin-like Growth Factor I (iv) Insulin-like growth factor bound to Protein 1 (v) Vasointestinal Peptide (vi) Vasopressin
19		Neuroendocrine function test	(i) Bombesin (ii) 17-Hydroxy-Ketosterone (iii) β-Endorphin (vi) Neurotensin (v) Somatostatin (vi) Substance P

20		Other Individual and Specific Hormones	(i) Gastrin (ii) Gonadotropin-releasing hormone (iii) Melatonin (iv) Pepsinogen (v) Adrenaline (vi) Dopamine
21		Anemia disease	(i) Erythropoietin (ii) Ferritin (iii) Folate (iv) Iron (v) Ability to carry iron (vi) Transferrin receptor
22		Vitamin	(i) Vitamin B1 (ii) Vitamin B2 (iii) Vitamin B6 (iv) Vitamin B12 (v) Vitamin D (Cholecalciferol) (vi) Intrinsic Factor (Blocking Antibodies)
23		Drug tracking	(i) Caffeine (ii) Benzodiazepines (iii) Penicillins (iv) Tetracyclines
24		Toxicology	(i) Amphetamines (ii) Cocaine (iii) Morphines (iv) Phencyclidine (v) Acetaminophen (vi) Catecholamines (vii) Ethanol (viii) Salicylate
25		Autoimmune diseases	(i) Antinuclear Antibody (ANA) (ii) Anti-topoisomerase (iii) Organ-specific autoantibodies (iv) Circulating immune complexes (v) TSH . receptor antibodies (vi) Antibodies against Cardiolipin
26		Signs of arthritis	(i) Anti-Streptococcal Hyaluronidase (ii) Anti-Streptokinase (iii) Anti-Streptolysin O (iv) C-Reactive Protein (v) Anti-Staphylolysin (vi) Anti-Streptococcal Screening
27		Liver function	(i) MEGX (ii) Carbohydrate Deficient Transferrin
28		Heart Mark	(i) Homocysteine (ii) ST2 (iii) Galectin-3 (iv) Myeloperoxidase (MPO)

29		Infection - Immune	(i) *Bacillus subtilis* (ii) *Pseudomonas Aeruginosa* (iii) *Helicobacter Pylori* (iv) *Lactobacillus easel*
30		Viral infection - Immune	(i) Norovirus (ii) Rotavirus (iii) *Hantavirus*
thirty first		Parasitic infections - Immune	(i) *Leishmania*
32		Fungal infections - Immune	(i) *Candida albicans* (ii) *Aspergillus*
33	Hematology/Hitology/ Cytology (Does not include blood test for blood transfusion)	Hemoglobin test	(i) Determination of Hemoglobin (Overall Hb) (ii) Fractional Oxyhemoglobin (FO2Hb) (iii) Fractionated Carboxyhemoglobin (FCOHb) (iv) Fractionated Methemoglobin (FMetHb) (v) Fractional Deoxyhemoglobin (FHHb)
34		General Coagulation Test	(i) Prothrombin time (ii) Thrombin time (iii) Activation Coagulation Time (iv) Partially Activated Thromboplastin Time
35		Hemostasis (Coagulation)	(i) Fibrinogen (ii) Protein C and Protein S Reagent (iii) C1 . Inhibitors (iv) Alpha-Antiplasmin (v) Fibrin (vi) Factor XIII (vi) Platelet Factor 4 (vii) Plasminogen
36		Other hematology tests	(i) Complete blood count (ii) Red blood cell rate (iii) Red blood cell sedimentation rate
37		Cytokines (Lymphokines)/Immune boosters	(i) Interferons (ii) Antigen/Solubilized receptor (iii) Tumor necrosis factor (iv) Cluster-promoting factors (vi) Tumor necrosis factor receptor
38		Histology Reagents/ Cytology	(i) Cell Staining (ii) Embedded, fixed, mounted media (iii) Dye Solution (iv) Immunohistochemistry Kit
39		Culture medium	(i) Dehydrated plant medium (DCM) (ii) Additives for DCM (iii) Prepared media (tubes, bottles, plates) (iv) Cells, media, serum for virus culture

40		Sensitivity Test Testing the susceptibility of bacteria to certain antibiotics	(i) Erythromycin susceptibility test for Staphylococcus aureus (ii) Tobramycin susceptibility testing for Pseudomonas aeruginosa (iii) Test for susceptibility to fungi
41		Biochemical medium identifier (ID)	(i) Gram Negative Manual ID (ii) Gram-positive Manual ID (iii) Other Manual ID Sets - Anaerobic, fastidious bacteria
42		Immune environment identifier	(i) Streptococcal Subtype Slip Test (ii) Serotype determination (E.coli, Salmonella, Shigella etc.)
43		Nucleic Acid (NA) based environmental identifier (ID)	(i) Streptococci (ii) Shigella
44		Serum Identifier (ID)	(i) For Parasitology and Mycology (Fungus and Yeast)
45		Bacterial infections (Detected by NA drugs)	(i) Streptococci (ii) Shigella
forty six		Viral infection (Detected by NA Reagent)	(i) NA Reagent for Influenza and Parainfluenza
47		Fungal infections	(i) NA Reagent for Mushroom (i) Candida albicans (iii) Aspergillus mushrooms

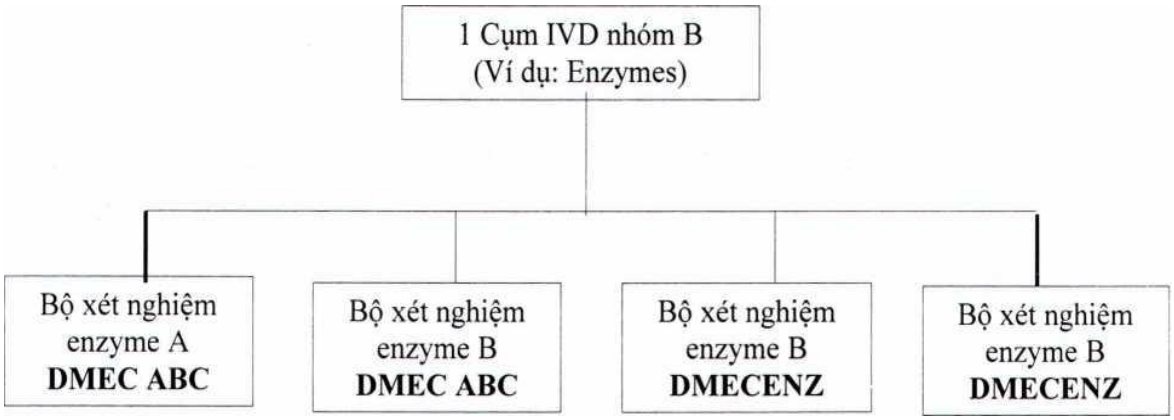
Diagram of grouping medical equipment by cluster IVD



If reagents or items are used with different groups, different IVD clusters can be grouped.

Example diagram of a group belonging to cluster IVD group B with 4 products in group Enzyme Cluster.

Example: Owner is “DMEC”



Based on this example, the 04 IVD products that meet the requirements for filing are the IVD cluster (Enzyme Cluster) and the names of the pharmaceutical products listed on the circulation registration number are as follows:

1. Enzyme Test Kit A* DMEC ABC

2. Enzyme Test Kit B** DMEC ABC

3. Enzyme Test Kit B*** DMEC ENZ

4. Enzyme Test Kit C**** DMEC ENZ

* Enzyme Kit A DMEC ABC where DMEC is the product owner and ABC is the ownership name.

* * Enzyme B DMEC ABC Kit where DMEC is the product owner and ABC is the proprietary name.

*** DMEC ENZ B Enzyme Assay Kit where DMEC is the product owner and ENZ is the proprietary name.

* *** Enzyme C DMEC ENZ Kit where DMEC is the product owner and ENZ is the proprietary name.

6. Other medical equipment sets

A set of other medical devices is a collection of two or more medical devices that are not classified as in vitro diagnostic medical devices that are labeled and supplied in a single packaging unit by the same owner. owned, the Department is determined:

- Have a proper name of the set;

- Labeled and supplied in a single packaging unit as specified by the product owner;

- Have a common purpose.

The list of medical devices in the set may differ in the number and combination of products forming the set registered for a single packer while retaining the name of the owner of the set and the purpose. use of the set.

The kit owner is responsible for the kit and its intended use, the kit owner can combine medical devices from other owners to become part of the kit to achieve a set purpose. general purpose. In the production and assembly of the kit, evidence to ensure the safety, quality, and effectiveness of the kit must be provided in the registration dossier. The relevant information to be submitted may include sterility, shelf life, proof of use and compatibility when used as a kit, quality management system, etc. Labels, specifically is the user manual, if any, the general purpose of the kit must be clearly stated.

Medical devices registered as part of a series must be registered as a single medical device

before being marketed as a single medical device for its own use or as a substitute.

If a medical device in one set is supplied for use in another set, the medical device must be included in the marketing record of that other set.

The name of the set must appear on the product label attached to the outer packaging of the set, the list of medical equipment included in the set must be indicated on the outer packaging of the kit or accompanying documents. The name of the kit is not required on the label of each medical device in the kit.

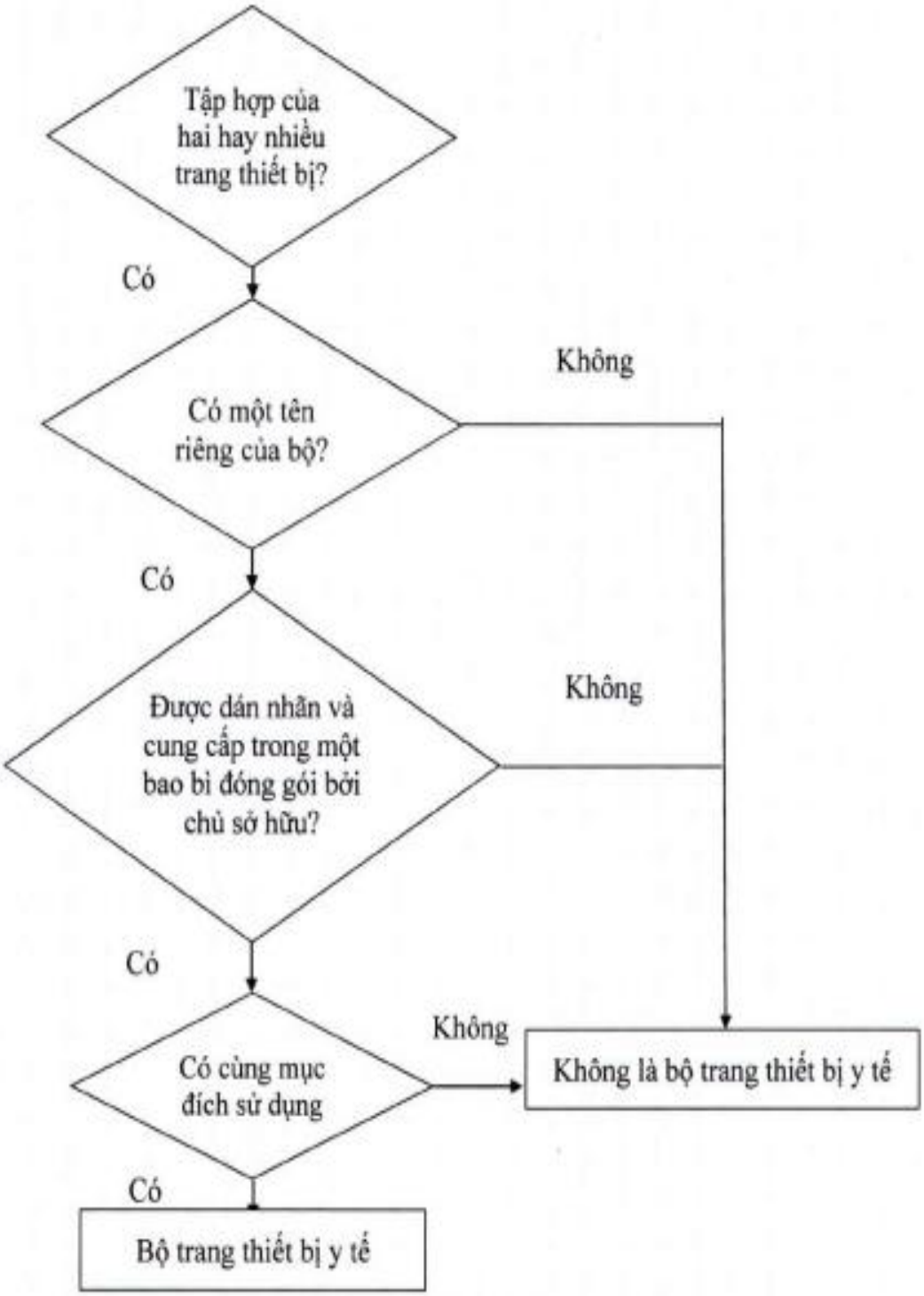
For example:

- A first aid kit consisting of medical equipment such as bandages, gauze, drapes and thermometers, when packaged together in a single packaging unit for a general medical purpose by a single product owner , can be registered as a set.

- One owner supplies custom dressing trays with different quantities and types of gauze and sutures to different hospitals. Once all the medical devices in the set are registered, the owner can customize the equipment in the kit for other hospitals, while keeping the set name and registered use. . The tray label must list the medical equipment provided in the tray. Some of the medical devices in the kit may be individually packaged and labeled, while others are unpackaged and may not be labeled.

- Promotional packaging or convenience packaging, without a set name and without a general medical purpose, including various quantities of medical devices. For example, general purpose solution, physiological saline solution, and contact lens case, will not be eligible for registration as a set, must register each medical device therein as medical devices. single economy.

Diagram of grouping of medical equipment by set



Appendix II

(Issued together with Circular No. 05 /2022/TT-BYT dated August 1, 2022 of the Minister of Health)

NAME OF FACILITIES

_____

Number: …

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

_____

… [1] .., *date....month....year 20...*

RESULTS OF CLASSIFICATION OF MEDICAL EQUIPMENT

_____

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

Pursuant to Circular No … /2022/TT-BYT dated ... August, 2022 of the Minister of Health detailing the implementation of a number of articles of Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on the management of medical equipment;

We classify medical devices as follows:

TT	Device name medical	Product category/code	Manufacturer, country of manufacture	Firm, owner country	Intended use as specified by the owner	The basis for classifying the level of risk	Level of risk classified

Legal representative of the establishment do the classification
(Signature, full name, title)
Confirmation by stamp or digital signature

_____

[1] Places