MINISTRY OF HEALTH OF VIETNAM	SOCIALIST REPUBLIC OF VIETNAM
-------	Independence – Freedom – Happiness

No. 05/2022/TT-BYT	*Hanoi, August 01, 2022*

CIRCULAR

ELABORATING DECREE NO. 98/2021/ND-CP DATED NOVEMBER 8, 2021 OF THE GOVERNMENT ON MANAGEMENT OF MEDICAL DEVICES

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

Pursuant to Decree No. 98/2021/ND-CP dated November 08, 2021 of the Government on management of medical devices;

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

Minister of Health promulgates Circular elaborating Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on management of medical devices.

Article 1. Scope

1. This Circular elaborates Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government on management of medical devices (hereinafter referred to as "Decree No. 98/2021/ND-CP").

a) Classification of medical devices under Clause 5 Article 5 of Decree No. 98/2021/ND-CP;

b) Addition to the list of in vitro diagnostic medical devices that are not required to undergo quality inspection by Vietnam's competent authorities under Point dd Clause 3 Article 30 of Decree No. 98/2021/ND-CP;

c) List of class B, class C, and class D medical devices purchased and sold as common commodities mentioned under Clause 1 Article 42 of Decree No. 98/2021/ND-CP;

d) List of medical devices to be inspected for safety and technical functions under Clause 10 Article 70 of Decree No. 98/2021/ND-CP;

dd) List of medical devices to be granted import permit under Point d Clause 2 Article 76 of Decree No. 98/2021/ND-CP.

2. Annuls documents on management of medical devices.

Article 2. Regulations on classification of medical devices

1. A medical device or multiple medical devices shall be classified in order to determine level of risks and be granted registration number.

2. The classification of a medical device or multiple medical devices must rely on the rules for classification using A, B, C, D levels of risks (details are prescribed under Appendix I attached hereto).

3. Sample of medical device classification results shall conform to Appendix II hereof.

Article 3. Addition to the list of in vitro diagnostic medical devices that are not required to undergo quality inspection by Vietnam's competent authorities under Point dd Clause 3 Article 30 of Decree No. 98/2021/ND-CP

1. Granted Certificate of Free Sale by any of the following countries, organizations:

a) Food and Drug Administration (FDA) - United States of America;

b) Therapeutic Goods Administration (TGA) - Australia;

c) Health Canada;

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

dd) Pharmaceuticals and Medical Devices Agency (PMDA) - Japan;

e) National Medical Products Administration (NMPA) - China;

g) Ministry of Food & Drug Safety (MFDS) - Korea;

h) EU member states as per Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

2. Granted registration number or certificate of registration, import permit for commercial purposes in Vietnam, except for cases where such items have been revoked.

3. Other than in vitro reagents, calibrators, control materials.

Article 4. List of class B, class C, and class D medical devices purchased and sold as common commodities mentioned under Clause 1 Article 42 of Decree No. 98/2021/ND-CP

1. Personal blood pressure monitors.

2. Fingertip pulse oximeter (SpO2).

3. Baby nasal aspirators.

4. Electronic thermometers, infrared thermometers.

5. Medical devices used to measure blood glucose: blood glucose monitoring device, lancing device, test strip, lancet, control solution, calibrators.

6. Nebulizers.

7. Medical tape, gauze pads.

8. Artificial tears classified as medical devices.

9. Condoms.

10. Vaginal contraceptive film (contains no drugs).

11. Vaginal lubricants classified as medical devices.

12. Electrical heating and cooling packs.

13. Class B in vitro diagnostic (ivd) medical device for self-testing.

14. In vitro diagnostic (ivd) medical device for self-testing of HIV, SARS-CoV-2.

Article 5. List of medical equipment to be inspected for safety and technical functions under Clause 10 Article 70 of Decree No. 98/2021/ND-CP

1. Ventilators.

2. Anaesthetic machines.

3. Electric scalpels.

4. Infant incubators.

5. Defibrillators.

6. Hemodialysis machines.

Article 6. List of medical equipment to be granted import permit under Point d Clause 2 Article 76 of Decree No. 98/2021/ND-CP

1. X-ray imaging devices.

2. Magnetic resonance systems.

3. Diagnostic ultrasound equipment.

4. Diagnostic endoscopy system.

5. Cyclotron system.

6. Diagnostic devices using radioactive isotopes (PET, PET/CT, SPECT, SPECT/CT, iodine concentration measuring instrument for I^{130}, I^{131}).

7. Autorefractors, ophthalmometers.

8. Electrophysiology equipment (EEG, ECG, EMG machines).

9. Electroretinography machines.

10. Bone densitometer.

11. Optical coherence tomography (OCT) machine; Non-mydriatic retinal camera.

12. Doppler fetal monitors.

13. Spirometers.

14. Biochemistry analyzers; Blood gas and electrolyte analyzers.

15. Hematology analyzers; Blood type analysis instruments.

16. Coagulation analyzers; Erythrocyte sedimentation rate analyzers.

17. ELISA test system.

18. Cellular extraction system.

19. Platelet aggregation and platelet function analyzers.

20. Microbial identification instruments.

21. Immunoassay analyzers.

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

23. Treatment devices using X-ray.

24. Endoscopic surgical system.

25. Radiotherapy equipment (Cobalt machine, Linear accelerator for cancer treatment, Gamma Knife, Brachytherapy equipment of all kinds).

26. Patient monitors.

27. Infusion pump; Electric syringe pump.

28. Scalpel (high voltage current, laser, ultrasound).

29. Surgical microscopes.

30. Prostatectomy surgery set.

31. Heart–lung machines.

32. Surgical navigation equipment.

33. Cryosurgery devices.

34. Infant incubators; Heaters for infants.

35. Anaesthetic machines.

36. Ventilators.

37. Implantable cardioverter-defibrillators.

38. Hyperbaric oxygen therapy chambers.

39. Extracorporeal/intracorporeal shock wave lithotripsy.

40. High Intensity Focused Ultrasound (HIFU) system.

41. Hemofiltration devices.

42. Ophthalmology surgical system (Laser Excimer, Phemtosecond Laser, Phaco, Vitreous cutter, Microkeratomes).

43. Glasses, contact lenses (myopia, hyperopia, mixed astigmatism) and contact lens solutions.

44. Laser devices for treatment in ophthalmology.

45. Long-term implantable devices and instrument (more than 30 days).

46. Invasive devices and instruments in cardiology and cranial nerve.

Article 7. Entry into force

1. This Circular comes into force from August 01, 2022.

2. Provisions elaborating Decree No. 98/2021/ND-CP under this Circular comes into force from the effective date of Decree No. 98/2021/ND-CP.

3. Form No. 13.01, Form No. 13.02 under Appendix I and Form under Appendix V of Circular No. 19/2021/TT-BYT dated November 16, 2021 of the Minister of Health expire from the effective date hereof.

4. The following documents expire from January 1, 2022:

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

b) Circular No. 46/2017/TT-BYT dated December 15, 2017 of the Minister of Health;

c) Circular No. 33/2020/TT-BYT dated December 31, 2020 of the Minister of Health;

d) Clause 1 Article 1 of Circular No. 23/2021/TT-BYT dated December 9, 2021 of the Minister of Health.

Article 8. Roadmap for implementation

1. For medical devices specified under Clauses 1, 2, and 3 Article 5 of this Circular:

a) In case these medical devices are procured after December 31, 2022, they must undergo safety and technical inspection as prescribed by Minister of Health;

b) In case these medical devices are procured before January 1, 2023, they must be adequately inspected before June 1, 2023 in accordance with the procedures promulgated by the Minister of Health.

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

a) In case these medical devices are procured after December 31, 2023, they must undergo safety and technical inspection as prescribed by Minister of Health;

b) In case these medical devices are procured before January 1, 2024, they must be adequately inspected before June 1, 2024 in accordance with the procedures promulgated by the Minister of Health.

Article 9. Organizing implementation

Chief of the Ministry Office, Chief Ministry Inspectorates, Directors, General Directors affiliated to the Ministry of Health, Directors of Departments of Health of provinces and central-affiliated

cities and other relevant organizations and individuals are responsible for the implementation of this Circular.

Difficulties that arise during the implementation of this Circular should be reported to the Ministry of Health for consideration./.

PP. MINISTER
DEPUTY MINISTER

Do Xuan Tuyen
