

MINISTRY OF HEALTH

No: 06/2022/TT-BYT

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

*Hanoi, August 1, 2022***CIRCULARS****Regulations on the list and issuance of circulation numbers for medical devices serving the prevention and control of COVID-19 epidemic in urgent cases**

Pursuant to Decree No. 75/2017/ND-CP dated June 20, 2017 of the Government regulating 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 medical devices management;

At the request of the Director of the Department of Medical devices and Constructions;

The Minister of Health promulgates a Circular stipulating the list and issuance of circulation numbers for medical devices serving the prevention and control of the COVID-19 epidemic in urgent cases.

Article 1. List of medical devices serving COVID-19 epidemic prevention and control in urgent cases according to the provisions of Clause 3, Article 29 of Decree No. 98/2021/ND-CP dated November 8, 2021 of the Government Government on medical devices management

1. PCR machine.
2. Chemicals (biological products) run the PCR machine to test for SARS-CoV-2.
3. Rapid test kit for antigen/antibody to SARS-CoV-2.
4. High-function ventilators, invasive and non-invasive ventilators, non-invasive ventilators, high-flow oxygen machines, portable ventilators.
5. Continuous dialysis machine.
6. Mobile X-ray machine.
7. Blood gas meter (measures electrolytes, lactate, hematocrite).
8. Máy theo dõi bệnh nhân ≥ 5 thông số.
9. Electric syringe pump; Infusion pump.
10. Defibrillator with pacemaker.
11. Blood clotting time meter.
12. Hemodynamic monitor.

Article 2. Supplementing the certificate of registration for circulation of medical devices of types C and D to serve the prevention and control of COVID-19 epidemic in urgent cases

Supplement the form of certificate of registration for circulation of medical devices of types C and D to serve the prevention and control of COVID-19 epidemic in urgent cases (specified in Appendix I attached to this Circular).

Article 3. Implementation effect

1. This Circular takes effect from August 1, 2022.
2. Circular No. 13/2021/TT-BYT dated September 16, 2021 of the Minister of Health regulating the issuance of circulation numbers and import of medical devices to serve the prevention and control of COVID-19 epidemic in In urgent cases, it ceases to be effective from the effective date

of this Circular.

Article 4. Transitional provisions

Applications for issuance of circulation registration certificates for type C and D medical devices serving COVID-19 epidemic prevention and control that have been received by the Ministry of Health before January 1, 2022 will continue. Resolved according to the provisions of Circular No. 13/2021/TT-BYT dated September 16, 2021 of the Minister of Health regulating issuance of circulation numbers and import of medical devices for epidemic prevention and control activities COVID-19 in case of emergency.

Article 5. Implementation organization

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

During the implementation process, 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 resolution./.

Recipients:

- Social Committee of the National Assembly;
- Government Office (Department of KGVX, Official Gazette, Government e-information portal);
- Ministry of Justice (Department of Inspection of Legal Documents);
- Ministries, ministerial-level agencies, and government agencies;
- Minister of Health (to report);
- Deputy Ministers of Health (to coordinate and direct);
- People's Committees of provinces and centrally run cities;
- Department of Health of provinces and centrally run cities;
- Department of Science and Technology of provinces and centrally run cities;
- Vietnam Social Insurance;
- Units under the Ministry of Health; health ministries and branches;
- Departments, Bureaus, General Departments, Ministry Offices, Ministry Inspectorates; Electronic information portal of the Ministry of Health;
- Save: VT, PC, TB-CT.

**KT. MINISTER
DEPUTY**

Do Xuan Tuyen

Appendix I

(Issued together with Circular No. 06/2022/TT-BYT dated August 1, 2022 of the Minister of Health)

MINISTRY OF HEALTH

Number:

SOCIALIST REPUBLIC OF VIETNAM
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Hanoi, date ... month ... year 20.....

**CERTIFICATE OF REGISTRATION FOR CIRCULATION OF MEDICAL devices OF TYPES C, D
FOR COVID-19 PREVENTION AND CONTROL IN EMERGENCY CASE**

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

Pursuant to Circular No. .../2022/TT-BYT dated August 2022 of the Minister of Health stipulating the list and issuance of circulation numbers of medical devices serving the prevention and control of COVID-19 epidemic in schools urgent case.

The Ministry of Health issues circulation registration certificates for medical devices (100% new) as follows:

1. Name of medical devices:
2. Trade name:
3. Global Medical Device Nomenclature - GMDN code (if any):
4. Type:
5. Product code (if any):
6. Packaging specifications (if any):
7. Type of medical devices:
8. Purpose of use:
9. Name and address of manufacturing facility:
10. Name and address of medical devices owner:
11. Name and address of the circulation number owner:
12. Name and address of warranty facility (if any):

The circulation number is valid from the date of signing to date....

Recipients:

.....

POSITION OF THE SIGNER

Sign (Write full name and title)

Confirmation by stamp or signature