MINISTRY OF HEALTH -------	SOCIALIST REPUBLIC OF VIETNAM Independence - Freedom - Happiness ----------
No. 46/2017/TT-BYT	*Hanoi, December 15, 2017*

CIRCULAR

GUIDELINES FOR THE GOVERNMENT'S DECREE NO. 36/2016/ND-CP DATED MAY 15, 2016 ON MANAGEMENT OF MEDICAL EQUIPMENT

Pursuant to the Government's Decree No. dated June 20, 2017 defining functions, tasks, entitlements and organizational structure of the Ministry of Health;

Pursuant to the Government's Decree No. 36/2016/ND-CP dated May 15, 2016 on management of medical equipment;

At the request of Director of Medical Equipment and Work Department,

The Minister of Health promulgates a Circular to provide guidelines for the Government's Decree No. 36/2016/ND-CP dated May 15, 2016 on management of medical equipment (hereinafter referred to as "Decree No. 36/2016/ND-CP").

Article 1. Scope

This Circular provides for:

1. Cases in which submission of the clinical trial datasheet and clinical trial result is not required when applying for registration according to Clause 1k Article 26 of Decree No. 36/2016/ND-CP.

2. Cases in which submission of the certificate of inspection of vitro diagnostic devices is not required when applying for registration according to Point l Clause 1 Article 26 of Decree No. 36/2016/ND-CP.

3. List of Type B, C, D medical equipment that may be traded as if normal goods according to Clause 1 Article 39 of Decree No. 36/2016/ND-CP.

4. Presentation of technical manuals of domestic medical equipment according to Form No. 01 in Appendix VIII of Decree No. 36/2016/ND-CP.

5. Instructions on translation of the authorization letter in Appendix VI of Decree No. 36/2016/ND-CP.

Article 2. Cases in which submission of the clinical trial datasheet and clinical trial result is not required when applying for registration of medical equipment

1. Type C and Type D invasive equipment specified in Appendix I hereof.

2. Type C and Type D equipment that have been registered and have the certificate of free sale issued by any of the countries or organizations on the list in Appendix II hereof.

Article 3. Cases in which submission of the certificate of inspection of vitro diagnostic devices is not required when applying for registration

Type C and Type D equipment that have been registered and have the certificate of free sale issued by any of the countries or organizations on the list in Appendix II hereof.

Article 4. List of Type B, C, D medical devices that may be traded as if normal goods

1. List of Type B, C, D medical equipment that may be traded as if normal goods is provided in Appendix III hereof.

2. Traders of Type B, C, D medical equipment that may be traded as if normal goods are not required to make the declaration of eligibility to trade in medical equipment.

Article 5. Presentation of technical manuals

Contents of section 1.1 of the technical manual provided in Form No. 01 in Appendix VIII of Decree No. 36/2016/ND-CP:

1. Operation principles and specifications, international standards, Vietnam's standards, national technical regulations and internal standards applied (these standards are the basis for inspection of effectiveness and safety of the medical equipment.

2. The internal standards used as the basis for inspection of effectiveness and safety of the medical equipment must satisfy the requirements specified in Circular No. 21/2007/TT-BKHCN on development and application of standards.

3. Sources of international standards (if any) must be specified.

Article 6. Translation of the authorization letter

Instructions on translation of the authorization letter in Appendix VI of Decree No. 36/2016/ND-CP in Appendix VI of Decree No. 36/2016/ND-CP are provided in Appendix IV hereof.

Article 7. Effect

This Circular comes into force from February 01, 2018.

Article 8. Transition

Technical manuals and authorization letters written in English language that are submitted together with the declaration of applied standards or application for registration and signed before the effective date of this Circular shall remain valid.

Article 9. Reference

In the cases where any of the documents referred to in this Circular is amended or replaced, the newer document shall apply.

Article 10. Implementation

Chief of the Ministry Office, Ministerial Chief Inspector, Directors of Departments affiliated to the Ministry of Health, Directors of Departments of Health, 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

Nguyen Viet Tien

APPENDIX I

IMPORTED MEDICAL EQUIPMENT WHOSE CLINICAL TRIAL DATASHEETS AND CLINICAL TRIAL RESULTS ARE NOT REQUIRED WHEN APPLYING FOR REGISTRATION

1. Peritoneal dialysis catheter

2. Catheter

3. Catheter kit

4. Cannulae

5. Guidewire

6. Introducer

APPENDIX II

LIST OF COUNTRIES AND ORGANIZATIONS WHOSE MEDICAL EQUIPMENT IS EXEMPT FROM SUBMISSION OF CLINICAL TRIAL DATASHEETS, CLINICAL TRIAL RESULTS AND VIETNAM'S CERTIFICATE OF INSPECTION

1. European countries:

- Republic of Austria;
- Republic of Poland;
- Portuguese Republic (Portugal);
- Republic of Bulgaria;
- Republic of Croatia;
- Republic of Estonia;
- Hungary;
- Hellenic Republic (Greece);
- The Republic of Ireland;
- Republic of Latvia;
- Federal Republic of Germany;
- Republic of Lithuania;
- Republic of Malta;
- The Republic of Finland;
- French Republic;
- Romania;
- Czech Republic;
- Republic of Cyprus;
- Slovak Republic;
- Republic of Slovenia;
- Spain;
- Italian Republic;
- Grand Duchy of Luxembourg;
- Swiss Confederation (Switzerland);
- Kingdom of England;
- Kingdom of Belgium;
- Kingdom of Denmark;
- Kingdom of the Netherlands;
- Kingdom of Sweden.

2. FDA (USA).

3. Japan.

4. TGA (Australia).

5. Canada.

APPENDIX III

LIST OF TYPE B, C, D MEDICAL EQUIPMENT THAT MAY BE TRADED AS IF NORMAL GOODS WITHOUT SUBMISSION OF DECLARATION OF ELIGIBILITY TO TRADE IN MEDICAL EQUIPMENT

1. Type B home-use in vitro diagnostic devices

2. Personal blood pressure monitors

3. Electronic thermometers, infrared thermometers

4. Personal blood glucose monitoring devices: blood glucose monitors, lancing devices, test trips, lancets, control solutions

5. Nebulizers

6. Adhesive bandages

7. Artificial tears classified as medical equipment

8. Condoms

9. Vaginal contraceptive films (drug-free)

10. Vaginal lubricants

11. Electric heat bags