The registration process is regulated by Regulation No. 1269 of 02.09.2008 "On state registration (re-registration) of medical devices and medical equipment".

The registration period is 6 months. The registration certificate is issued for a period of 5 years.

**The organizational structure of the health care system in the examination of the registration of medical equipment and medical devices consists of the following:**

1. Ministry of Health of the Republic of Belarus;
2. UE "Center for Expertise and Testing in Health Care".

**The main examination process for the registration of medical equipment and products medical purpose consists of the following stages:**

- Reception of documents;
- conducting the initial examination of the documents contained in the registration dossier;
- inspection of the production of medical devices and medical equipment;
- Sanitary and hygienic testing of these products and equipment of domestic and foreign production;
- technical tests of medical products and medical equipment of domestic production;
- Specialized examination of documents required for the state registration (re-registration) of medical devices and medical equipment, amendments to the registration dossier for medical devices and medical equipment previously registered in the Republic of Belarus;
- clinical trials of medical devices and medical equipment, appointed by the Ministry of Health and other studies.

**The necessary list of documents for registration of Medical devices and Medical equipment:**

1. Documents submitted for state registration (re-registration) of medical products and medical equipment of domestic production must meet the following requirements:
   - application for state registration (re-registration) of medical devices and medical equipment;
   - technical regulatory legal acts of the manufacturer for medical devices, medical equipment with verification methods (for measuring instruments);
   - protocols and (or) acts of technical tests of medical devices and medical devices;
   - protocols and (or) acts of sanitary-hygienic testing of medical devices and ME;
   - protocols and (or) acts of clinical trials of MD and ME;
   - instructions for the use of medical devices or instructions for the operation of MD, a description (sample or breadboard model) of marking, packaging of medical devices and ME.

2. Documents submitted for state registration (re-registration) of medical products and medical equipment of domestic production must meet the following requirements:
   - application for state registration (re-registration) of medical devices and ME;
   - technical regulatory legal acts of the manufacturer for medical devices, medical equipment with verification methods (for measuring instruments);
   - protocols and (or) acts of technical tests of medical devices and medical devices;
   - protocols and (or) acts of sanitary-hygienic testing of medical devices and ME;
   - protocols and (or) acts of clinical trials of ME and MD;
inструкции для использования медицинских устройств или инструкции по эксплуатации MD, а также описание (прототип или образцовый образец) маркировки, упаковки медицинских устройств и MD.

3. Документы, поданные для внесения изменений в регистрационную картотеку медицинских устройств и медицинского оборудования, ранее зарегистрированных в Республике Беларусь, должны соответствовать следующим требованиям:

   • заявление о внесении изменений в регистрационную картотеку медицинского оборудования и медицинских устройств;
   • сертификат о согласии на изменения, внесенные производителем, выдаваемый на бланке производителя, указанного в зарегистрированном (ре-регистрации) MD и ME.

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