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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;

- 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 MD.

3. Documents submitted for making changes to the registration dossier for medical devices and medical equipment previously registered in the Republic of Belarus must meet the following requirements:

- an application to amend the registration dossier on medical equipment and medical devices;
- The certificate of justification of the changes introduced by the manufacturer is made out on the company's letterhead of the manufacturer of registered for registration (re-registration) of MD and ME.

MedExpert Kazakhstan is the holder of the International Quality Certificate ISO 9001: 2015, issued by the international organization TUV SUD Managment Service GmbH.