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# Registration of medical devices and medical equipment

On November 28, 2021, amendments to the resolution of the Ministry of Health of the Republic of Belarus of April 23, 2015 No. 55 "Instruction on the procedure for carrying out a complex of preliminary technical works preceding state registration (re-registration) of medical devices and medical equipment, amendments to the registration dossier for medical products and medical equipment" are enforced.

Among the changes, the exclusion from the scope of the Instruction for regulating a set of technical work related to the conduct of examinations, inspection of the production of medical devices, tests and other studies for the registration of medical devices in the EAEU. Also, residents of the Great Stone Industrial Park were excluded from the scope of regulation.

It is additionally specified in relation to what a complex of preliminary technical works is being carried out. For example, medical products and medical equipment of domestic production; medical products and medical equipment of foreign production; medical products and medical equipment of foreign production in circulation in the United States of America and the member states of the European Union.

The appendix contains a list of documents of the registration dossier and the requirements for them.

More details can be found at the following link:

<https://pravo.by/document/?guid=12551&p0=W22137368&p1=1&p5=0>

## Locations

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