

ANNEX FOR

to the Regulations on the procedure for registration of medicinal products
means and products of medical purpose and
issuance of registration certificate

SCROLL

documents provided for registration of a medical device in Uzbekistan

1. List of submitted documents.
2. Power of attorney from the manufacturer enterprise to an official authorized to conduct registration proceedings.
3. General information about the medical device.
4. The registration certificate of a medical product (if the medical device was previously registered).
5. Normative document, including the order and methods of testing a medical product, a standard for similar products.
6. For production of batch production, the draft standard of organization / pharmacopeia article, technological regulations, technological instruction.
7. Passport for medical equipment, analytical passport for a medical device.
8. Technical description of medical equipment.
9. Information on laboratory tests, technical tests, preclinical studies and clinical (medical) tests.
10. Test methods, programs and protocols (for sterile medical products - tests conducted over the past year) on medical devices.
11. Information on the compliance of the medical device with international standards (if any).
12. Methods of testing medical equipment (for measuring devices).
13. Information on the absence of infectious agents in "in vitro" - diagnostic tools prepared from human blood.
14. Information on stability in storage and transport of "in vitro" - diagnostic tools.
15. Illustrated advertising materials, brochures, catalogs, photo size not less than 13x18cm.
16. A sample of a medical device (in sufficient quantity to carry out the tests in accordance with the normative document).
17. Protocol of analysis of the provided series of medical products.
18. Colored graphic models of primary and secondary packaging.

The above documents are submitted to the Main Department in two copies.

Copies of documents must be readable and certified with the seal and signature of the head of the organization.