

List of documents and materials for the State registration (renewal) of the medical devices (devices of medical purpose)

1. Content (list of the documents below).
2. Application from Manufacturer or its representative (please find it on our website).
3. Electronic version of the list of products that are applied for registration with catalogue numbers
(in language of applicant and Ukrainian).
4. Power of Attorney (or part of the contract) issued from manufacturer to Applicant (if they differ) that can confirm relations between companies.
5. Instruction (user manual) of the medicinal product.
6. Certificate of origin.
7. Information regarding standards, normative bases that justified the manufacture of the product (if applicable).
8. Materials for determination of the safety-class of the product depending on the level of potential risk.
9. Information on preclinical trials.
10. Information on clinical trials.
11. Brochures, catalogues of the product.
12. Conclusion on the results of the state metrological attestation – only for metering (scales, thermometers etc.) products.
13. Package design or sample of the marking for the product.
14. Copy of the registration certificate of the Applicant (state registration of the company).
15. Document that confirm payment of the state fee.

Since we are experienced in registration procedure, we advise you to add some additional documentation that can be useful for speeding up the procedure:

16. Technical passport.
17. Documents (national or international), that confirm adequacy of the product(s) to the requirements of the national or international normative documents and characterize the manufacturing conditions.
18. Certificate of adequacy for products, issued in accordance with Ukrainian legislation (if applicable).
19. Protocols of safety, quality and efficiency research (if applicable).
20. Documents that confirm state registration in the manufacturer's country, notary legalized and apostilled.

Note: All documents have to be submitted in three copies (original plus 2 copies or notary certified copies) with Ukrainian translation, confirmed with the stamp of the Applicant.