

List of documents for the registration of medical devices

1. Name/Address of the finished medical device product manufacturer.
2. Power of Attorney. Certified by The Apostille.
3. Legal Status of Commercial registration of the manufacturing facilities. Notarized.
4. Certificate/letter - explanation of product origin.
5. Manufacturer Declaration of quality confirm stating that the product complies with Medical Device Directive 93/42EEC of 14 June 1993 or any other applicable directive guidelines. on the company's letterhead. Original or notarized copy.
6. Certificates that applicable to your country: FDA (mandatory for USA origin), Free Sales, ISO 9001, 13485 2003 (mandatory for all countries). Notarized.
7. Conformity Declaration (Letter of Assurance) stating that the applicant complies with Medical Device Directive 93/42EEC of 14 June 1993 or any other applicable directive guidelines. Performed by relevant Authorities.
8. Clarification of Catalogue Numbers of device as laid down in Annex IX of Medical Device Directive 93/42EEC of 14 June 1993. On the company's letterhead.
9. Certificate of analysis/conformity/quality On the company's letterhead, stamped and signed by QA Manager.
10. Patient leaflet/Instruction for use.
11. Product(s) specification/Specification sheet.
12. Pre-clinical and clinical data.
13. Technical data/dossier (if available).
14. The results of microbiological tests and toxicology information (if applicable).
15. Sterility and validation data (for sterile forms).
16. Samples.
17. Mock-ups/ images of product secondary & primary package (preferably as in printed view and in jpg format)
19. Brochures, catalogues

- 1. All mentioned data is mandatory. Other legal, scientific, technical data with regard to applied product could be required in process of evaluation in accordance with expert opinion;*
- 2. Samples & materials intended for registration in Ukraine to be imported with special permission from Health Authorities.*

*Attach all necessary documents to your letter and email to **info@alenpharm.com***

See also:

Pharmaceuticals

<http://www.alenpharm.com/docs/pharmaceuticals.pdf>

Cosmetics

<http://www.alenpharm.com/docs/cosmetics.pdf>

BAA

<http://www.alenpharm.com/docs/baa.pdf>