



List of documents required for State registration of medical device in Ukraine.

1. Application*
2. List of all modifications, models, parts, disposables that will be shipped as a parts of medical device, with (and for) medical device or will be shipped to Ukraine later.
3. **Power of Attorney issued on the name of Cratia***
4. Instructions for use, user's manual, technical characteristics.
5. Brochure (description of the device with a photo) or catalogue of devices.
6. Certificate of origin issued on the headed paper of manufacturer.
7. **Certificate of State registration of medical devices in manufacturer's country (Exportation certificate or Free sales certificate).**
8. Certificates of registration from other countries (Russian Federation, other CIS countries).
9. **Certificate of state registration of manufacturer(s) legal entity (usually that document is issued by Chamber of Commerce or by other state authority).**
10. **Manufacturing license, other applicable manufacturer's certificates.**
11. **CE certificate.**
12. **Certificate of compliance to Directive 93/42/EEC or relevant Directive for IVD (Declaration of conformity with mentioned safety class referred to Directive 93/42/EEC).**
13. **Certificates ISO 9001; ISO 13485. Other standard compliance certificates.**
14. Protocols of the preclinical and clinical studies, other studies and scientific information. Literature (articles) on medical use of the device. Recommendation letters from doctors regarding use of medical device. Any other evidences of safety and efficiency use of medical device in other countries.
15. Certificates of analysis/quality (if applicable).
16. If sterility is applied - certificate of sterility, description and validation of sterilization method.
17. Labeling information according to international standard EN 980.
18. **Certificate of state registration of Applicant's legal entity (usually that document is issued by Chamber of Commerce or by other state authority), if Applicant is different from manufacturer.**
19. **Document that explains relations between Applicant and manufacturer, if Applicant is different from manufacturer. It can be Power of Attorney, Letter of Authorization etc.**

* - will be prepared by Cratia Ltd. and sent to Applicant for adoption.

Points 3, 7, 8, 9, 10, 11, 12, 17 and 18 - should be notary certified copies (for some countries an apostil or legalization in the Council of Ukraine can be required).

If you will have any questions – please do not hesitate to contact us:

Telephone: +38 (044) 332 42 94

Telephone/fax: +38 (044) 361 48 28

E-mail: info@cratia.com.ua

Web: www.cratia.com.ua

Address: Frunze str. 1/3, 3-rd entrance, 4-th floor, 04080, Kiev, Ukraine