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Registration of Medical Device

Obligatory requirement for import and sale of the medical devices in Ukraine is a state authorization (registration). State agency responsible for registration of the medical device is a State Department of regulatory policy of medicinal products and goods in healthcare area of Ministry of Health of Ukraine (hereinafter – State Department). State Department has taken responsibilities after elimination of State Agency of medicinal products and medical devices in February 2009.

Registration certificate for medical device is valid for 5 years for the date of state registration.
Registration certificate consist from two parts:

- Registration certificate itself (includes number & date, date of expiry, name of medical device, custom commodity code that should be applied to the device with all modifications, safety class of the device).
- Annex to registration certificate that includes listing of all modifications (type, size, color, version etc.) of medical device and accessories (parts, disposables, regents etc.) that are supplied with medical device

Application for renewal of registration should be submitted not earlier than 120 and not later than 90 days.

Following particularities can be applied to different types of medical devices:

Taxation: devices that are free of VAT tax and devices that are objects of VAT tax;
State purchases: general group of devices and devices that can be purchased on state tenders;
Types: general group of medical devices, devices for in-vitro diagnostic (IVD), active implants;
Safety class: class I, class IIa, class IIb, class III;
Custom commodity code: classification is performed upon group, type and way of use of medical device;

New registration of medical device requires following steps to be done (in brief):
1. Translation and preparation of the dossier, preparation of the Application and Annex (with listing of all modifications);
2. Receipt of the decision of the Chamber of commerce of Ukraine regarding custom commodity code for the device. Correct code should be chosen in order to avoid problems during custom clearance. Custom commodity code determines if the medical device will be free from VAT tax or not.
3. Submission of the Application and the dossier to the State Department.
4. Preliminary expertise of the dossier (presence of all documents).
5. Technical expertise of the registration materials: detailed expertise of registration dossier.
6. Safety (preclinical, toxicological) studies: expertise of safety of medical device.
7. Specific studies (for some types of medical devices): sterility studies, measuring (metrological) studies etc.
8. Efficiency (medical, clinical): expertise of examination of efficiency of medical device.
9. After positive conclusions from all studies a medical device is included to the log of nearest session of State Department.
10. Inclusion of medical device to the State registry of medical devices, issue of the original registration certificate and Annexes.

Session of the Stare Department is held every two weeks.

The registration procedure is based on the following legislation:

1. Ratification of Registration procedure of medical equipment and medical products Order of the Cabinet of Ministers of Ukraine No.1497 dated on 09.11.2005
    1. State registration procedure of medical products in Ukraine Order of the Ministry of Health of Ukraine No.229 dated on 26.09.2000

Structure of the registration dossier:

1. Application
2. Annex to Application
3. Power of Attorney*
4. Instruction, user's manual, catalogues, technical characteristics.
5. Certificate of registration of the medical device in manufacturer's country.*
6. Certificate of origin or/and Free sales certificate.*
7. Manufacturing license, other manufacturer's certificates.
8. CE certificate (Certificate of compliance to Directive 93/42/ EEC)*.
9. Declaration of conformity with mentioned safety class referred to Directive 93/42/ EEC .
10. Certificates ISO 9001; ISO 13485. Other standard compliance certificates .*
11. Protocols of the preclinical and clinical studies, other studies and scientific information.
12. Certificates of analysis/quality. Certificates for starting materials (frames).
13. Sterility certificate is applied, validation of sterility.
14. Labeling information.

* - Points 3, 5, 6, 8, 10 should be notary certified copies.

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