

Application Form

Mr. Galatenko N.A.
Head of
CAB Private Company «POLYTOX»

Request for estimate correspondence (certification) of management system

Applicant:

Organization Name (full and short)	
Statutory address	
Phone/fax/e-mail/web	

Accredited representative:

Organization Name (full and short)	
Statutory address	
Phone/fax/e-mail/web	

represented by

(First Name, Last Name, Position)
apply, that ERP system adopted according to the requirements

(normative document indexes and names)

- First-time rating/certification**
- Recertification**
- Supervision of certificated management system**
- Expending certification**
- The reduction of scope of certification**
- The change in the scope of certification**

Standard-conform:

- DSTU ISO 13485:2005 Medical products. Quality Management System. Regulation requirements (ISO 13485:2003, IDT)**
- DSTU EN ISO 13485:2015 Medical products. Quality Management System. Regulation requirements (EN ISO 13485:2012, IDT; ISO 13485:2003, IDT)**
- ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes**
- DSTU ISO 9001:2015 Quality Management System. Requirements**

2. Contact person: (Full name, phone/fax/ e-mail) _____

3. Year of management system adoption _____

4. Certification field of management system _____

5. Branches availability Yes No

If "Yes", their addresses, phones/faxes/e-mails for each separately:

6. Requirements elicitation of standards DSTU EN ISO 13485:2015, DSTU ISO 9001:2015 (if available): _____

7. Information about existing certificate of management system: _____

8. Product (service) name, for which certification (evaluation) of management system is provided _____

9. Normative documents indexation according to which products (services) produced: _____

10. Consulting company information, advisers and other, who were involved to the development and(or) adoption of quality management system: _____

11. Information about all processes, which is implemented by other organizations (outsourcing): _____

12. Applicant is committed to:

- fulfill all conditions of certification and provide all necessary information;
- use all reasonable efforts to conduct an audit;
- agree with the participation of observers (e.g. employees of accreditation agency or auditors-in-training);
- cover all expenses related to certification works of Quality Management System, without regards to the result;
- keep up with requirements, set up by approved Quality Management System;
- support approved Quality Management System and its effectiveness;
- analyze attempt of products usage after its introduction.

13. The applicant is aware of rules and procedures of CABs Private Company «POLITKOS» regarding works of certification/evaluation of management system and support certifications, as well as support grievance.

14. The applicant guarantee, that he is not applying for Quality Management System certification of products production, which is indicated in this application form, to other certification authorities.

15. The applicant considers next documents as private:

- All provided documents;
- Documents related to internal Quality Management System;
- Organizational documents.

16. Desired dates of certification audit fulfillment:

First-time rating _____

Final rating _____

17. Applicant details.

Payment account
Bank
MFO (sort code)
USREOU
Certification for VAT №
Taxpayer identification №
Tax payer (on general grounds or other)

17. Documents attached to the application form: questionnaire, copies of all documents according the list (duly certified), letter of explanation of enterprise.

Head of the Enterprise

(signature)

(Full Name)

Chief Accountant

(signature)

(Full Name)