Applicant letterhead

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

Application form № «____»_____year.
(filled by CAB)

Conduction of products evaluation accordance to technical regulations requirements

1 MANUFACTURER-APPLICANT

Name of Manufacturer	
Address	
Phone/fax/ e-mail	
Head of company full name:	
Phone/fax/ e-mail	
Contact person full name:	
Phone/fax/ e-mail	

2 ACCREDITED REPRESENTATIVE

Full Name	
Address	
Phone/fax/ e-mail	

3 Request for conformance evaluation of product conformity to specified requirements:

☐	Technical regulations for medical products
☐	Technical regulations for medical products for diagnostics in vitro
☐	Technical regulations for active medical products, which is implementing

4 Information about products, for which compliance verification will be made:

(filled for each type, product category)

Name of the product		
Product Reference Document		
List of standards, which is approve product correspondence to the technical rules in case of free usage		
Product purpose		
Series production	☐ YES	☐ NO
First introduction into service (date), country		

Product refers to:	☐ I class ☐ II a class ☐ II b class ☐ III class
	☐ medical products for diagnostic in vitro ☐ List A ☐ List B ☐ products for self-control
	☐ active medical products, which implements
	☐ system of medical products / medical procedure set
Product type	☐ aseptic ☐ contain pharmaceutical products ☐ contain animal origin tissue ☐ contain human hemoderivatives ☐ with measurement function
Industrial capacity: Address phone/fax/ e-mail	

5 Compliance assessment should be made according to next procedures and its combinations:

☐ support of Quality Management System operations with project review
☐ support of complex Quality Management System without project review
☐ type review
☐ product review
☐ support of Quality Management System operations during production
☐ support of Quality Management System
☐ internal production control

5.1 Product testing proposed to be made at:

_____

(Address of testing laboratory/center)

6 The applicant obliged:

● to fully observe conditions of technical regulations, procedures of compliance assessment, provide stability of measurements (characteristics) of product as well as meet all conditions of certification and provide any information, which is necessary for certification;
● meet requirements approved by Quality Management System;
● support proper conditions for work/use of approved Quality Management System;
● systematically analyze experience received while using products after putting it in operation and establish appropriate means to realize necessary corrective actions;
● inform Conformity Assessment Body in case of any planned changes in Quality Management System, products, technical project;
● inform relevant authorities, CABs about incident appearance regarding products immediately after getting noticed about it:
1) about any breakdowns or performance degradation and/or functional quality of product, and any mismatch of information in operation manual, which might lead to consumer death or aggravation;
2) about any cause of technical or medical nature, related with characteristics or functional properties of product, which leads to systematic products recall by manufacturer;
- provide all necessary documents and be responsible for the adequacy of information in provided materials.
6.1 Applicant aware with arrangements of conformance evaluation and grievance procedure.

6.2 Applicant guarantee:

● that the same application for technical regulations compliance assessment of product was not sent to any other allocated agency;

● that provided information in this application is true;

● cover all expenses related with work performance of technical regulations compliance assessment, not depending on its results;

6.3 Applicant agree that sample of products will not be returned in case of destructive test administration of this product.

7 Applicant require to prepare Document of Compliance in Ukrainian, and _____language (*if necessary*).

8 Applicant considers next documents as privat:

☐ All provided documents;

☐ Documents related to internal Quality Management System;

☐ Organizational documents

9 Applicant details.

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

Documents attached to the application form:

1. Package of technical normative documents and Quality System Management documents (duly certified), which is claimed by certain technical regulations which is corresponds to selected compliance verification procedure – with execution of listed documents in two copies, for both sides.
2. Application form for Quality Management System certification (on a point of order with Quality Management System evaluation)
3. Questionary (*on a point of order with Quality Management System evaluation*)

Head of the Enterprise _____ _____ _____
(signature) (date) (Surname)

Chief Accountant _____ _____ _____
(signature) (date) (Surname)