Conformity Assessment Body Private Enterprise "POLYTOX"

Questionnary
For preliminary evaluation of Quality Management System according to DSTU EN ISO 13485:2015 (EN ISO 13485:2012, IDT; ISO 13485:2003, IDT) DSTU ISO 13485:2005 (ISO 13485:2003, IDT)

1. Details of manufacturer-applicant Company:

Full and short name of manufacturer-applicant Company	
Statutory address	
Actual address of manufacture	
Phone/fax/ e-mail/web	

2. Information about corporate structure and management team of manufacturer-applicant

Position and Full Name of Head of the Enterprise	
Phone/fax/ e-mail	
Position and Full Name of executive manager representative (head of quality)	
Phone/fax/ e-mail	
General number of employees (persons)	
Number of employees (persons) involved in QMS	

3. Information about Quality Management System (QMS)

3.1. Year of Quality Management System entry_____
3.2. Specification sphere of Quality Management System:_____.
_____
3.3 Main product consumer:_____
3.4 General description of Quality Management System is included to the main documents:_____
_____

3.5 Information about existed certificates of Quality Management System:_____

4. Information about product production:

4.1 Organizational structure of the company with the list of names of Heads of structural departments which is include principal offices and auxiliaries, engineer and administrative services with indicated connections between, number of employees *(provide in attachment as a scheme).*
4.2 List of company areas and employees covered with Quality Management System:
(provide in attachment as a table):

Location of manufacture, its branches and work centers, address/phone/fax/e-mail for each separately		Departments/ Number of employees								General number of employees/ covered with QMS	Number of changes:
		Management	Engineering and development	Procurements	Manufacture	Control	Sales	Operations	Other		
1										/	
2										/	

4.3 Information about types of business activities/processes which can influence on products/services correspondence and which is made by subcontractors (outsourcing):

Processes	Names and locations of subcontractors which is make processes passed to third executives
Engineering and development	
Manufacture	
Packing	
Sterilization	
Stowage	
Operations	
Other	

4.4. If there are regulatory requirements DSTU ISO 13485, which is not used in sphere covered by QMS (**yes** / **no**)**:**

If yes, please specify which requirements is not used and explain:

_____

_____

5 Product characteristics:

	Questions regarding Quality Management System	DSTU ISO 13485:2005	Short answer (yes/no)	Document reference
1.	Is QMS established, documented, implemented and supported and is its effectiveness supported? Are main processes of QMS indicated?	4.1		
2.	Is work policy in quality field formed? Is policy of quality sphere include obligations to correspond and support the effectiveness of QMS?	4.2.1, 5.3		
3.	Are targets fixed in a quality sphere in the shape of measurement rate?	4.2.1, 5.4.1		
4.	Is "quality manual" approved? (in-service date)	4.2.1, 4.2.2		
5.	Is file for each type or model of medical product, which contains or identifies documents for determination of product specification and QMS requirements established and supported? Do these documents define all manufacturing process including assembling and technical support?	4.2.1		
6.	If there is documented paperwork of management procedure?	4.2.3		
7.	If there are documented protocols of management procedure for providing proofs of compliance to requirements and effectiveness of QMS?	4.2.4, 7.1d		
8.	Are requirements for risk management during product realization documented? Are results of risk management documented in the minutes?	4.2.4, 7.1		
9.	Are there documented procedures of internal audit?	8.2.2		
10.	Are there documented management procedures of the product (service) non-conformity?	8.3		
11.	Are there documented procedures of corrective actions establishment?	8.5.2		
12.	Are there documented procedure of preventive actions establishment?	8.5.3		
13.	Which documents (except quality and QMS methods manual) company used for secure planning, functioning and controlling of the processes? (prepare as attachment to this application form)	4.2.1		
14.	Does Top Management provide proofs of the fulfillment of its commitments regarding elaboration and implementation of QMS and its effectiveness support aimed to stable production of safe and effective products?	5.1		
15.	Are results of QMS evaluation registered by Top Management?	4.2.3, 5.6.1		
16.	Is data about education, proficiency training, and qualification and experience determined and registered?	6.2.2, 6.4c		
17.	Are requirements for products (services) as well as requirements of the client and specified conditions determined?	7.2.1, 7.6		
18.	Is product (service) requirements evaluated?	7.2.2		
19.	Are methods of engineering and development of products documented?	7.3.1		
20.	Is incoming data of requirements to the product (service) while engineering and developing determined and documented?	7.3.2		
21.	Is out coming data of product (service) engineering and developing registered?	7.3.3		

22.	Are results of project engineering and developing evaluation registered?	7.3.4		
23.	Are results of correspondence between incoming and outcoming data evaluation registered?	7.3.5		
24.	Are results of engineering and developing approval registered?	7.3.6		
25.	Is data of evaluation of changes in project development registered?	7.3.7		
26.	Are results of supplier evaluation and protocols of supplier evaluation registered?	7.4.1, 7.4.3		
27.	Does company support protocols of procurement?	7.4.2		
28.	Are requirements of working space, health condition, cleanliness of staff clothing, conditions of working space and proper staff preparations determined and documented?	6.4		
29.	Are protocols for each batch determined and kept in the record, which is guaranteed possibility of tracking and identify the quantity of products?	7.5, 7.5.1.3,7.5.3		
30.	Are special requirements to the product cleanliness and pollution control determined?	7.5.1.2		
31.	Are documented requirements which are containing criteria for accepting assembling and checking of the medical product determined? Are protocols of assembling registered?	7.5.1.2.2,4.2.4		
32.	Are procedures, protocols, control materials and control measurement methods for product service and evaluation determined? Are service protocols registered?	7.5.1.2.3, 4.2.4		
33.	Are protocols of parameters of sterilization process which are used for each sterilizing batch kept? (Refers to aseptic medical products).	7.5.1.3, 4.2.4		
34.	Are facts of loss or damage (if any) of products, which belongs to the client registered?	7.5.4		
35.	Are special storage conditions of a product controlled and registered?	7.5.5		
36.	Are results of tools of measurement equipment calibration and evaluation registered?	7.6.		
37.	Is information about clients' level of satisfaction monitored?	8.2.1		
38.	Are results of internal audit registered?	8.2.2		
39.	Are processes monitored and measured?	8.2.3		
40.	Are product characteristics monitored and measured? Is personality, which is control or test implants and active medical products which can be implanted, registered?	8.2.4		
41.	Are discrepancies founds of a product (service) registered? Are protocols of personality, who is authorized for concession, registered?	8.3		
42.	Are protocols of data evaluation results registered?	8.4		
43.	Are protocols of all clients grievance researchers registered? Are results of corrective action registered?	8.5.1, 8.5.2		
44.	Are results of preventive actions registered?	8.5.3		

5.1. Name of the product (service) for certification (evaluation) of Quality Management System _____.

5.2. Indexes of normative documents, according to which products (services) produced:

_____

5.3. Main technical processes, which are used at manufacture (methods of product production):_____

5.4. Testing technique which is used at the own laboratory:

_____

6. Environmental control conditions:

Does your production take place in special environmental conditions? ☐ yes ☐ no

If yes, what parameters or areas are managed and controlled?

- ☐ temperature
- ☐ humidity
- ☐ number of particles (total particle counts)
- ☐ microbiological particles (microbial counts)
- ☐ ESD controlled zones
- ☐ zones which are protected from radiation
- ☐ other

Did you meet all requirements "clean room"? ☐ yes ☐ no

If yes, define ISO classification according to ISO 14644: _____

7. Aseptic products specifications:

Did you produce aseptic products? ☐ yes ☐ no

If yes, which type of sterilization did you use?

- ☐ ethylene oxide according to ISO 11135 / DSTU ISO 11135
- ☐ exposure according to ISO 11137/ DSTU ISO 11137
- ☐ moist heat according to ISO 17665-1 / DSTU ISO 13683
- ☐ aseptic processing
- ☐ other:

Are there sterilization validation process implemented? ☐ yes ☐ no

8. General questions regarding Quality Management System

8. Other information

8.1 Staff languages:
8.2 Web-site:

Management representative _____
(signature) (full name)
(date)

Head of company _____
(signature) (full name)
(date)