

LIST OF DOCUMENTS,
Which are attached to the application for certification of Quality Management System
according to the requirements of
DSTU EN ISO 13485:2015 (EN ISO 13485:2012, IDT; ISO 13485:2003, IDT)
DSTU ISO 13485:2005 (ISO 13485:2003, IDT)

№	Document Name	Availability
1	2	3
1.	Extract from United State Register of Legal Entities and Individual Entrepreneurs of Ukraine, copy of statute, copy of certification for VAT	<input type="checkbox"/>
2.	Company organizational structure	<input style="border: 1px solid red;" type="checkbox"/>
3.	Copy of staffing schedule	<input type="checkbox"/>
4.	Policy and targets at quality sphere	<input type="checkbox"/>
5.	List of QMS procedures and description of their interaction	<input type="checkbox"/>
6.	Copies of quality manual (Handbook Quality) according to ISO 13485	<input type="checkbox"/>
7.	Copies of main procedures according to the ISO 13485	<input type="checkbox"/>
8.	Documents which contain requirements for the risk management while product realization	<input type="checkbox"/>
9.	Results of clinical product assessments	<input type="checkbox"/>
10.	Results of preclinical product assessments (protocols of toxicity tests by security factors)	<input type="checkbox"/>
11.	Test reports (electromagnetic compatibility, electric safety etc.)	<input type="checkbox"/>
12.	The protocol of the last analysis by Top Management.	<input type="checkbox"/>
13.	Program of internal audit. Copies of last protocols of internal QMS audits.	<input type="checkbox"/>
14.	List of normative documents according to which products are produced.	<input type="checkbox"/>
15.	Technical specifications (technical file)	<input style="border: 1px solid red;" type="checkbox"/>
16.	Information about claims (reclamations) from customers for the last year	<input type="checkbox"/>
17.	Product Catalog (if available)	<input type="checkbox"/>
18.	Certificates of conformity , CE certificate	<input type="checkbox"/>
19.	Numbered list of documents provided to CAB	<input type="checkbox"/>

Notes: column 3 is filled by Conformity Assessment Body(CAB) Pr.Ent. "POLYTOX";
CAB Pr.Ent. " POLYTOX " reserves the right to request, if necessary, additional documents after examining the documentation and questionnaires.