PHARMALEX
REGULATORY AFFAIRS · UZBEKISTAN

PHARMALEX Private Enterprise
7a/31 Yangi Olmazor Street, Almazar District,
Tashkent, 100000, Uzbekistan
(+998) 94 050 66 88 | info@pharmalex.uz
www.pharmalex.uz

Documents required for state registration of medical devices

Uzbekistan · Medical device classes by safety level

No.	Documents	I	IIa	IIb	III	Note
1	An application in accordance with Appendix 2 to the Regulation on the Procedure for State Registration of Medical Devices. When the application is submitted through a representative, a document confirming the authority of the representative (power of attorney).	+	+	+	+	The power of attorney must be notarized or have an apostille stamp or be certified by a consulate.
2	Technical documentation of the medical device:	+	+	+	+	
2.1	Information about the medical device: scope, brief description, types and brief description of the medical device and its components, if available, the medical device nomenclature (GMDN) and the unique device identifier (UDI);	+	+	+	+	
2.2	Information about the medicines contained in the medical device (composition, quantity of the medicine, compatibility of the medicine with the medical device, information about the registration of the medicine in the country of manufacture). (*) (**)	+	+	+	+	(*) the documents listed in these paragraphs are not required for software. (**) the documents listed in these paragraphs are not required for in vitro diagnostic devices.
2.3	A copy of the document granting the right to manufacture in the country of origin (if any). Information about the manufacturer: a list of divisions and subsidiaries with the name, type of activity, legal address, form of ownership, management structure, status and powers.	+	+	+	+	
2.4	Creation and production information: technical drawing, scheme of production processes, main stages of production, packaging, testing and the procedure for releasing the finished product into free circulation. Regulation of the production of domestic medical device manufacturer. (*)	+	+	+	+	(*) the documents listed in these paragraphs are not required for software.
2.5	A list of standards or general specifications (with information about them) to which a medical device must comply.	+	+	+	+	
2.6	Regulatory document for foreign “in vitro” diagnostic medical device, normative document (draft) for domestic “in vitro” diagnostic medical device. (*)	+	+	+	+	(*) the documents listed in these paragraphs are not required for software.

PHARMALEX Private Enterprise
7a/31 Yangi Olmazor Street, Almazar District,
Tashkent, 100000, Uzbekistan
(+998) 94 050 66 88 | info@pharmalex.uz
www.pharmalex.uz

No.	Documents	I	IIa	IIb	III	Note
2.7	Risk management and analysis report.	+	+	+	+	
2.8	Information on the sterilization process, including process validation, test results for micro-organisms (bioburden level), bacterial endotoxins, specifying test methods for determining sterility (if necessary) and information on packaging validation. (*) (**)	+	+	+	+	These documents are for sterile products. (*) the documents listed in these paragraphs are not required for software. (**) the documents listed in these paragraphs are not required for in vitro diagnostic devices.
2.9	Information on the compliance of the medical device with the general requirements for safety, efficiency, marking and use documentation (general requirements)	+	+	+	+	
2.10	Information on test reports (verification) and validation conducted in order to prove compliance with general technical requirements of the medical device					
2.11	Reports on specificity and sensitivity tests for in vitro diagnostic medical devices. (*)	+	+	+	+	(*) the documents listed in these paragraphs are not required for software.
2.12	Information on the absence of infectious agents in “in vitro” diagnostic medical devices made from biological material. (*)	+	+	+	+	(*) the documents listed in these paragraphs are not required for software.
2.13	Information about specific software (if available): verification and validation results, information about the software architecture and life cycle, cybersecurity measures (integrity control, access control, data protection and prevention of unauthorized interference), identification and marking, manufacturer test results, and a monitoring system for compliance with requirements.	+	+	+	+	
2.14	Stability study report - for products with a shelf life, with a translation of test results and conclusions into the official language. (*)	+	+	+	+	(*) the documents listed in these paragraphs are not required for software.

PHARMALEX Private Enterprise
7a/31 Yangi Olmazor Street, Almazar District,
Tashkent, 100000, Uzbekistan
(+998) 94 050 66 88 | info@pharmalex.uz
www.pharmalex.uz

No.	Documents	I	IIa	IIb	III	Note
2.15	Adverse events and withdrawal reports (this information is not provided for newly developed and designed medical devices): a list of adverse events associated with the use of the medical device, in cases where a series of adverse events have occurred, the time period during which the reported events occurred, a brief description of each event and the total number of events of each type reported, a plan for resolving the problems and a coordination plan developed by the manufacturer for their elimination in each of these cases (if available). A plan for collecting and analyzing data on the safety and efficacy of medical devices in the post-registration phase.	+	+	+	+	
2.16	Reports of studies (tests) on the assessment of biological effects of medical devices, conducted in order to prove their compliance with general biological requirements. (*) (**)	+	+	+	+	(*) the documents listed in these paragraphs are not required for software. (**) the documents listed in these paragraphs are not required for in vitro diagnostic devices.
2.17	Biosafety information. (*)	+	+	+	+	(*) the documents listed in these paragraphs are not required for software.
2.18	A report proving the clinical efficacy and safety of a medical device.	-	+	+	+	Clinical efficacy is not required for safety class I medical devices (with the exception of sterile, measuring and invasive medical devices).
2.19	Information on marking and packaging (13-18 cm color mock-ups with dimensions, labeling text (in the state language and in Russian or English for foreign manufacturers). (*)	+	+	+	+	(*) the documents listed in these paragraphs are not required for software.
2.20	The instructions for use or operational manual of the medical device are in the state language and in Russian or English.	+	+	+	+	
3	A copy of the current certificate (according to ISO 13485 standard) issued to the manufacturer’s quality system.	+	+	+	+	Shall be issued by a valid and accredited organization
4	Declaration of Conformity to Safety and Performance Requirements.	+	+	+	+	

PHARMALEX Private Enterprise
7a/31 Yangi Olmazor Street, Almazar District,
Tashkent, 100000, Uzbekistan
(+998) 94 050 66 88 | info@pharmalex.uz
www.pharmalex.uz

No.	Documents	I	IIa	IIb	III	Note
5	A certificate of registration of the medical device in the country of manufacture or a document confirming its registration (certificate for free circulation, export certificate (with translation into the state language) or a copy of a document confirming its registration in other countries.	+	+	+	+	
6	Photographs of the medical device (showing product appearance, components, consumables and materials) and catalogs (*).	+	+	+	+	(*) the documents listed in these paragraphs are not required for software.
7	Production study (inspection) report.	+	+	+	+	
8	A protection document (certificate, patent and annex thereto) confirming the intellectual property rights (trademarks and industrial designs) used in the medical device, or an agreement on their use, or a conclusion from an authorized body in the field of intellectual property on the trade name and design of the medical device.	+	+	+	+	

Notes

The applicant may omit certain information from the documents with justification.
Several modifications of a medical device may be included in one registration certificate.
An application to extend the validity of a registration certificate must be accompanied by conclusions from clinical facilities in the Republic of Uzbekistan on the safety and effectiveness of the medical device.