PHARM
CONSULT

LIST OF REQUIRED DOCUMENTS FOR MEDICAL DEVICES REGISTRATION IN KAZAKHSTAN:

No.	Document name	Note
1.	Document certifying registration in the manufacturing country or manufacturing site (Registration Certificate, Free Sale Certificate, Export Certificate) with an authentic notarized translation into Russian (except for medical devices manufactured in the Republic of Kazakhstan for the first time)	In accordance with international notarial certification standards or standards of notarial certification established in the Republic of Kazakhstan, format: PDF
2.	A copy of the approval of the right to manufacture in the manufacturing country, with an attached authentic translation into Russian for manufacturers in Kazakhstan and CIS countries, for other countries if available	In accordance with international notarial certification standards or standards of notarial certification established in the Republic of Kazakhstan, format: PDF
3.	List of documents certifying registration in other countries, indicating the number and date of issue (if any) with an authentic translation into Russian	To be certified by the manufacturer or its authorized representative, format: PDF
4.	Copies of certificates for quality management system of the manufacturer of medical devices (ISO 13485, GMP or relevant regional or national standard) with an authentic translation into Russian	In accordance with international notarial certification standards or standards of notarial certification established in the Republic of Kazakhstan, format: PDF
5.	Declaration of conformity with the safety and efficacy requirements for a medical device or an equivalent document with an authentic translation into Russian	In accordance with international notarial certification standards or standards of notarial certification established in the Republic of Kazakhstan, format: PDF
6.	Document confirming the class according to the degree of potential risk of use (Declaration of Conformity; justification letter of the manufacturer) with an authentic translation into Russian	To be certified by the manufacturer, format: PDF
7.	Information on medicines as a part a medical device (composition of the medicine, amount, information on compatibility of the medicine with the medical device, document confirming the quality of the drug substance) with an authentic translation into Russian	To be certified by the manufacturer, format: PDF
8.	Data on the biosafety of a medical device containing materials of animal or human origin, based on material analysis, as well as information on the selection of sources (donors), material selection, processing, storage, testing, initial examination of testing procedures, as well as the handling of tissues, cells, substances of animal or human origin, microorganism and virus cultures with authentic translation into Russian	To be certified by the manufacturer, format: PDF
9.	Toxicological test report (protocol) with an authentic translation into Russian of the results and conclusions of testing in accordance with ISO 10993 of medical devices and (or) accessories, components and consumables for medical devices in contact with the surface of the human body, mucous membranes, the internal environment of the body;	To be certified by the manufacturer, format: PDF
10.	Technical test report (protocol) with an authentic translation into Russian of the test results and conclusions; For electrical medical devices: electrical safety, electromagnetic compatibility testing. Radiation safety reports in case of ionizing radiation	To be certified by the manufacturer, format: PDF
11.	Stability test report substantiating the shelf life of medical devices, as well as sterile accessories and consumables included in the package of medical equipment with an authentic translation into Russian of the test results and conclusions, including In-use shelf life. The test includes stability in vivo in open bottle and/or, for automated instruments, stability in the working position. Transport stability The following information is described: (a) test report (including protocol, acceptance criteria); b) test method under simulated conditions; c) conclusions and recommended transport conditions. Stability test report for reagents and consumables included in the package of in vitro (IVD) diagnostics medical device of closed type	To be certified by the manufacturer, format: PDF

12.	Specificity and analytical sensitivity test report or data for in vitro (IVD) diagnostics medical device, including those included in the package of in vitro (IVD) diagnostic medical device of closed type (if applicable to the declared type of medical device), including, if applicable errors (uncertainty), detection and quantification limits, measurement range, linearity, threshold value	To be certified by the manufacturer
13.	Data on clinical (clinical and laboratory) trials (studies) with an authentic translation of the test results and conclusions or available clinical data (scientific publications).	To be certified by the manufacturer, format: PDF
14.	Information on monitoring of adverse and undesirable events (information is not provided for newly developed and designed medical devices) with an authentic translation into Russian; 1) a list of adverse events (accidents) related to the use of the device and an indication of the period of events; 2) summaries for each type of event and an indication of the total number of events of each type reported (if many); 3) a list of recalled medical devices and/or explanatory notices providing an analysis of corrective actions and measures taken	To be certified by the manufacturer or its authorized representative, format: PDF
15.	Quality document: international, national or corporate standard (technical specifications, specification of control methods for the finished product) with an authentic translation into Russian of the specification and test methods	To be certified by the manufacturer, format: PDF
16.	Information on the software (if available): results of software validation, data on its verification and primary examination, including information on its development and testing at the enterprise and in multicenter studies, data on the identification and labeling of the operating system: (a) specify the software name. b) specify the software version. The version tested must be accurately identified, and this version corresponds to the final version of the software supplied,. Provide a description of the software, including determination of those functional characteristics of the device that are controlled by the software, the hardware platform, the operating system (if applicable), the use of packaged software (if applicable).	To be certified by the manufacturer, format: PDF
17.	Certificate with a description of a scope of application, purpose, summary of medical device characteristics, presentation and components (according to form)	To be certified by the manufacturer or its authorized representative, format: pdf (as part of the dossier), Excel - separately.
18.	Operational document of medical equipment, approved in the manufacturing country (original version) with authentic translation into Kazakh and Russian	The document approved in the manufacturing country shall be certified by the manufacturer. Authentic translations into Kazakh and Russian shall be certified by the authorized representative, format: PDF
19.	Instructions for use of the medical device, approved in the manufacturing country with an authentic translation into Russian	To be certified by the manufacturer, format: PDF
21.	Samples of medical device	According to Appendix 3 to the Rules for the Examination of a Medical Device
22.	Standard samples (if indicated in the quality document)	
23.	Graphic representation of a label for medical equipment	To be certified by the manufacturer, format: PDF
24.	Description of medical device packaging (Information on packaging, including, primary, secondary, group, transport, intermediate packaging; provide information (for example, material, composition, size) Documents regulating the quality of medical device packaging materials (quality specification, certificate of analysis for primary packaging) with an authentic translation into Russian	To be certified by the manufacturer, format: PDF
25.	Photo (gives the appearance of the product, accessories, consumables)	To be certified by the manufacturer, format: JPEG

26.	Color layouts of packages and labels (primary, secondary and (or), group packages) from the manufacturer (provided in expanded form). If there are a large number of sizes, colors, it is allowed to provide a model layout for one of the sizes, color (if the layouts are identical)	For medical devices. To be certified by the manufacturer, format: PDF, JPEG
28.	A copy of Marketing Authorization in the Republic of Kazakhstan (when re-registering and amending)	format: PDF
29.	Justification letter for the type of in vitro diagnostics medical device (open or closed system) with an authentic translation into Russian	To be certified by the manufacturer, format: PDF
30.	Information on the sterilization procedure, including information on the primary examination of the process, results of testing for the content of microorganisms (biological burden degree), pyrogenicity, sterility (if necessary) with an indication of testing methods and information on the initial examination of the package with an authentic translation into Russian.	To be certified by the manufacturer, format: PDF
31.	Information on the manufacturer: name, type of activity, legal address, form of ownership, list of subdivisions and subsidiaries with their status and authority with an authentic translation into Russian	To be certified by the manufacturer or its authorized representative, format: PDF
32.	Information on development and production: schemes of production processes, main stages of production, packaging, testing and final product release procedures with an authentic translation into Russian	To be certified by the manufacturer, format: PDF
33.	List of standards applicable to the medical device (with information about them) with an authentic translation into Russian	To be certified by the manufacturer
34.	Plan for the collection and analysis of data on the safety and effectiveness of the medical device in the post-approval period with an authentic translation into Russian	To be certified by the manufacturer
35.	Risk analysis report with an authentic translation into Russian	To be certified by the manufacturer
36.	Marketing information (history, subject to the market circulation of a medical device for more than 2 years) (if any)	To be certified by the manufacturer