List of required documents for registration in Kyrgyzstan

№	Name of document	Medical product class				Medical device for in vitro diagnostics (regardless of potential risk class)	Note
		1	2a	2b	3		
1	A power of attorney from the manufacturer authorizing to represent the organization's interests in the course of the registration (if necessary)	+	+	+	+	+	* In accordance with international certification standards
2	A copy of the permit for manufacturing operations in the country of origin with an appendix attached (if available)	+	+	+	+	+	* In accordance with international certification standards
3	Copies of quality management system certificates of medical devices manufacturer (ISO 13485 or a relevant regional or national standard) (if available)	+	+	+	+	+	* In accordance with international certification standards
4	A declaration of conformity to requirements for safety and efficacy of medical devices or an equivalent document (if any)	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)

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5	A copy of the registration certificate/marketing authorization issued in the manufacturer's country with a certified translation into Russian (if available)	+	+	+	+	+	* In accordance with international certification standards
6	A copy of the document certifying the registration in other countries (if any)	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)
7	Data on labeling and packaging (full-color package mock-ups and label layouts, labelling text in the official and/or state language)	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)
8	GTIN Barcode (EAN13; for unique identification of the product) (if any)	+	+	+	+	+	
9	Information on the development and production: flowcharts of manufacturing processes, major stages of production, packaging, testing and release of the final product	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)
10	Information about the manufacturer: name, type of activity, legal address, form of incorporation	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)

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11	Reports of accidents and recalls (the information is not provided for newly designed and engineered medical devices): - a list of adverse events or accidents related to the use of the product, specifying the period during which such events occurred in case of an excessive number of adverse events, brief overviews of each of the types of events shall be provided specifying the total number of events of each type so reported; a list of recalls from the medical devices market and (or) explanatory notices and description of the approach to addressing such issues as well as solution thereof by manufacturers in each specific case; a description of analysis and (or) corrective actions taken in response to the above cases	+	+	+	+	+ (except for Class 1)	Certified by the manufacturer (authorized representative thereof)

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		1	2a	2b	3		
12	A list of standards which the medical device meets (including information about such standards)	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)
13	Information on the compliance of the medical device with general requirements for safety and efficacy of medical devices, requirements for labeling thereof and respective operation manuals	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)
14	The document setting out requirements for technical characteristics of the medical device	+	+	+	+	+	
15	Protocols of technical testing conducted to prove compliance with the general requirements	+	+	+	+	+ (except for reagents, reagent kits)	
16	Reports of studies (trials) assessing the biological effect of the medical device carried out to prove compliance with the general requirements	+	+	+	+		

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17	A report of the clinical evidence of the efficacy and safety of the medical device	+	+	+	+	+ (except for Class 1)	Certified by the manufacturer (authorized representative thereof)
18	A risk analysis report		+	+	+	+ (except for Class 1)	Certified by the manufacturer (authorized representative thereof)
19	Data on medicinal products contained in the medical device (medicinal product composition, quantity, data on compatibility with the medical device, medicinal product registration in the country of origin)	+	+	+	+		Certified by the manufacturer (authorized representative thereof)
20	Data on biological safety (if available)	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)
21	Data on sterilization procedure, including information on the process validation, results of testing for microorganisms content (degree of biological burden), pyrogenicity, sterility (if necessary),	+	+	+	+	+ (except for Class 1)	Certified by the manufacturer (authorized representative thereof)

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	specifying the test methods and package validation data (for sterile devices)						
22	Information about dedicated software, information about the software validation provided by the manufacturer (if any)	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)
23	A stability study report with an authentic translation into Russian of tests results and findings for products with a shelf-life established	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)
24	An operation manual or instructions for use of the medical device	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)
25	A service manual (in terms of medical device components) in case of absence of data in the operating documentation (if any)	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)

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26	A report of the production site inspection (if available)	+	+	+	+	+	
27	A plan for the acquisition and analysis of data on post-registration safety and efficacy of medical devices (if any)	+	+	+	+	+	Certified by the manufacturer (authorized representative thereof)
28	Documents confirming the results of testing of medical devices for the purpose of measuring instruments type approval (for medical devices classified as measuring instruments) (if necessary)	+	+	+	+	+	

* (International certification standards for states that are parties to the Hague Convention abolishing the requirement for the use of foreign official documents dated October 5, 1961 - apostilization; for states that are not parties to the Hague Convention - legalization by consular services (notarization); for the CIS countries - notarization).