The list of documents of the registration dossier for the examination of a medical device according to the order of the Minister of Health of the Republic of Kazakhstan dated November 18, 2009 No. 736

On approval of the Rules for the examination of medicinal products and medical devices

(with amendments and additions as of April 19, 2019)

№	Document title	Class 1	Class 2a	Class 2b	Class 3	Remark
1	2	3	4	5	6	8
1.	Document certifying the registration in the country-manufacturer or production site (marketing authorization, certificate of free sale, certificate for export) with the authentic translation into Russian, notarized (except for medical devices produced in the Republic of Kazakhstan for the first time)	+	+	+	+	In accordance with international certification standards or certification standards established in the Republic of Kazakhstan format: PDF
2.	Copy of an authorization document for the right to manufacture in the country-manufacturer (if available) with an annex and the authentic translation into Russian	+	+	+	+	In accordance with international certification standards or certification standards established in the Republic of Kazakhstan format: PDF
3.	List of documents certifying the registration in other countries with the indication of a number and date of issue (if available) and the authentic translation into Russian	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF
4.	Copies of certificates for the quality management system of the manufacturer of medical devices (ISO 13485, GMP or corresponding regional or national standard) with the authentic translation into Russian	- (except for sterile)	- (except for sterile)	+	+	format: PDF
5.	Declaration of conformity with the requirements for safety and efficacy of medical devices or equivalent document (if available) with the authentic translation into Russian	+	+	+	+	format: PDF
6.	Document confirming the class depending on the degree of potential risk of use (declaration of conformity; letter - justification from the manufacturer) with the authentic translation into Russian	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF

7.	Data on medicinal products in the composition of the medical device (composition of the medicinal product, quantity, data on the compatibility of the medicinal product with the medical device, document confirming the quality of the medicinal substance) with the authentic translation into Russian	-	+	+	+	Certified by the manufacturer or its authorized representative format: PDF
8.	Report (protocol) of toxicological and hygienic tests with the authentic translation of the results and conclusions of tests for the medical device and components that come in contact with mucous membranes or with skin, into Russian	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF
9.	Technical test report (protocol) with the authentic translation of test results and conclusions into Russian	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF
10.	Report on stability studies, justifying the shelf life (for medical devices, including those that are part of sterile components), with the authentic translation of the results and conclusions of tests into Russian	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF
11.	Data on clinical (clinical and laboratory) tests (studies) with the authentic translation of test results and conclusions into Russian or available clinical data (application, reviews, scientific publications)	-	+ (in presence of the medicinal product)	+	+	Certified by the manufacturer or its authorized representative format: PDF
12.	Information about the monitoring of adverse and undesirable events (information is not provided for newly developed and designed medical products) with the authentic translation into Russian: 1) a list of undesirable events/accidents associated with the use of the device, and an indication of the period of events; 2) brief reviews of each type of events and the indication of total number of events of each type for which reports have been received (in case of the large quantity);	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF

	3) a list of withdrawn medical devices and/or explanatory notices with the provision of analysis of corrective actions and measures taken					
13.	Regulatory document: international, national or organization standard (technical conditions, specification of finished product control methods) with the authentic translation of specifications and test methods into Russian	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF
14.	Certificate with the description of the scope, function, summary of the medical device, versions and components (under the form)	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF, DOC, Excel
15.	Instructions for the use of medical device approved in the country of origin with the authentic translation into Russian	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF
16.	Draft instruction on the medical use of medical device in Kazakh and Russian	+	+	+	+	Certified by the applicant format: PDF, DOC
17.	Samples of the medical device	+	+	+	+	
18.	Standard samples (if specified in the regulatory document)	+	+	+	+	
19.	Description of the packing of the medical device (Information about the packing, including primary, secondary, group, transport, intermediate packing); it is necessary to provide the information (for example, material, composition, size) Documents regulating the quality of packing materials of the medical device (quality specification, certificate of analysis for the primary packing) with the authentic translation into Russian	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF
20.	Photo (displays the appearance of the product, components, consumables)	+	+	+	+	Certified by the manufacturer or its authorized representative format: JPEG

21.	Color layouts of packing and labels (for primary, secondary packing) from the manufacturer for the medical device or its components, if necessary (development of a packing layout is provided in the expanded form). In presence of a large number of unit sizes, colors, it is allowed to provide a standard layout for one of the sizes, color (if the layouts are identical)	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF, JPEG
22.	Draft text of the layout of packing, label, sticker of the medical device in Kazakh and Russian (in case of a large number of sizes, colors, approval of one layout using abbreviations is allowed)	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF, DOC, JPEG
23.	Copy of the marketing authorization in the Republic of Kazakhstan (in case of re-registration)	+	+	+	+	format: PDF
24.	Biosafety data (if available) with the authentic Russian translation	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF
25.	Data on the sterilization procedure, including information on the primary process examination, results of the test for the content of microorganisms (degree of biological load), pyrogenicity, sterility (if necessary) with the indication of test methods and data on the primary packing examination (for sterile products) with the authentic translation into Russian	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF
26.	Information about the manufacturer: name, type of activity, legal address, form of ownership, list of subdivisions and subsidiaries, indicating their status and authority with the authentic translation into Russian	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF
27.	Information about the development and production: diagrams of production processes, main stages of production, packing, testing and procedure for the release of the final product with the authentic translation	+	+	+	+	Certified by the manufacturer or its authorized representative format: PDF

	into Russian					
28.	List of standards which the medical device corresponds to (with the indication of information about them) with the authentic translation into Russian	+	+	+	+	Certified by the manufacturer (its authorized representative)
29.	Plan for the collection and analysis of the data on safety and efficacy of the medical device in the post-registration period with the authentic translation into Russian	+	+	+	+	Certified by the manufacturer (its authorized representative)
30.	Risk analysis report (if available) with the authentic translation into Russian	-	+	+	+	Certified by the manufacturer (its authorized representative)
31.	Marketing information (history provided that the medical device has been in the market for more than 2 years) (if available)	–	–	+	+	Certified by the manufacturer (its authorized representative)

Compilation of a certificate for the medical device **

Name	Manufacturer (producer), country Production site, country Authorized representative of the manufacturer, country	Completeness				Scope, function	Brief specification
		Name of components	Model	Manufacturer	Country		
		Master unit (if available)					
		Accessories (if available)					
		Constituent parts (if available)					
		Expendable materials (if available)					
		Software (if available)					