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List of documents for registration of a medical device according to the requirements of the Eurasian Economic Union:

1	Application form for expertise (link «Application for a Medical Device expertise in the Eurasian Economic Union») Application form for a Medical Device registration (link « Application for a Medical Device registration in the Eurasian Economic Union»)»)	originals
2	Power of attorney from the manufacturer having the right to represent interests during registration procedure - (if necessary)	In accordance with the international certification standards or certification standards established according to the legislation of the member state of the Eurasian Economic Union (further – member state)
3	- A copy of the authorization document for the right to manufacture in the country of origin (if any)	A copy of the authorization document for the right to manufacture in the country of origin (if any)
4	Medical device manufacturers certificates copies for the quality management system (ISO 13485 or appropriate regional or national standard of a member-state)- (if any)	In accordance with the international certification standards or certification standards according to the legislation of the member sate
5	Declaration of compliance to the general requirements of a medical device safety and efficacy or the equivalent document (if any)	
6	Registration certificate copy (free sale certificate, export certificate (except medical devices for the first time manufactured on the territory of the member-state)), issued in the country of origin (if any) including Russian translation	In accordance with the international certification standards or certification standards according to the legislation of the member sate
7	Copy of the document certifying the registration in other countries (if any)	Certified by the manufacturer (his authorized representative)
8	Medical device reference describing the area of application and purpose, medical device short specification, performing variants and accessories (in shape)	Certified by the manufacturer (his authorized representative)
9	Labeling and packaging data (full-color layouts of packages and labels, marking, translation text in Russian and state languages of the member states)	Certified by the manufacturer (his authorized representative)
10	Designing and manufacturing information: production process schemes, main production stages, packaging, testing and final product output procedure	Certified by the manufacturer (his authorized representative)

11	Manufacturer information: name, type of business activity, juridical address, type of the ownership, managerial staff, the list of departments and affiliated companies indicating their status and full powers	Certified by the manufacturer (his authorized representative)
12	Marketing information (with condition of product's background circulation on the market more than 2 years) (if any) - (except for the 1st and 2nd A class)	Certified by the manufacturer (his authorized representative)
13	Accidents and reference reports (this information is not supplied for the new developed and designed medical devices): The list of undesirable events and accidents associated with the use of the device and an indication of the period of time during which these accidents occurred, If the listing of undesirable events exceeds then it is necessary to represent short reviews on each of the type of the events and to indicate total number of each type of the reported events, reference lists from the medical device market and (or) explanatory letters and approach description for the problems analyses and their manufacturers decisions in each of the named above cases, Reviews description and (or) improving activities taken as the appropriate reaction, - (except for the 1st class)	Certified by the manufacturer (his authorized representative)
14	The list of standards of a corresponding medical device (indicating information about them)	Certified by the manufacturer (his authorized representative)
15	Medical device compliance information to the general safety requirements and their efficacy, labeling requirements and operational documentation for them (further – general requirements)	Certified by the manufacturer (his authorized representative)
16	A document establishing requirements for the technical characteristics of a medical device	
17	Technical testing protocols held aiming to prove the general requirements compliance (excluding reagents and reagent kits)	
18	Examining protocols (tests) on the medical device biological impact assessment, carried out in order to prove compliance with the general requirements	
19	Medical device clinical efficacy proof and safety report (except for the1st class)	Certified by the manufacturer (his authorized representative)
20	Risk analysis report - (except for the 1st class)	(except 1st class)
21	Data on medicines as a part of a medical device (medicines composition, quantity, data on the medicines compatibility with a medical device, medicine registration procedure in the country of the manufacturer)	Certified by the manufacturer (his authorized representative)
22	Biological safety data (if any)	Certified by the manufacturer

		(his authorized representative)
23	Data on the sterilization procedure, including information on validation process, test results for the content of microorganisms (bioburden degree), pyrogenicity, sterility (if necessary) with an indication of the test methods and packaging validation data (for sterile products - (except for the 1st class)	Certified by the manufacturer (his authorized representative)
24	Special software data (if any): manufacturer software validation data	Certified by the manufacturer (his authorized representative)
25	Stability testing report – with an authentic Russian translation of the device testing results and conclusions with a shelf life included	Certified by the manufacturer (his authorized representative)
26	Medical device operational application or instruction in the state language of the states of recognition (if necessary) and Russian translation included	Certified by the manufacturer (his authorized representative)
27	Service manual (in terms of a medical device components) – in case of operational documentation data absence (if any)	Certified by the manufacturer (his authorized representative)
28	Production inspection report (if any)	
	Collecting and data analyzing plan of medical devices safety and efficacy at the post-sale stage	Certified by the manufacturer (his authorized representative)
29	Documents confirming medical devices testing in order to approve the type of measuring instruments (regarding medical devices related to measuring instruments the list of which is approved by the Commission (if necessary)	
30	Copies of the documents confirming the payment and expertise results, medical device registration in a reference sate	

Certification form for medical devices according to the requirements of the Eurasian Economic Union

Name	Manufacturer(country)	Completeness				Application area, purpose	Brief description of a medical device
		Name of the components	model	manufacturer	country		
		1. main blocks (parts of a medical device)					
		2Accessories (if any)					
		3. Consumables (if any)					
		4. Component materials (if any)					