List of documents for the registration of in-vitro medical devices in the Russian Federation

No	Document	How to approve	Comments
1	Power of attorney from the manufacturer, confirming the authority of the Authorized Representative in the Russian Federation for the implementation of registration actions.	By apostill	Our company prepares, sends for approval and signature to the manufacturer
2	Documents on the registration of the manufacturer and its production sites in the country of the manufacturer.	By apostill	Provided by the manufacturer
3	Letters on behalf of the manufacturer of the contract with other production sites (if there are other sites).	By apostill	Provided by the manufacturer
4	Certificate confirming compliance of production conditions with international norms and standards ISO 13485, ISO 9001.	By apostill	Provided by the manufacturer
5	Documents confirming the compliance of the medical device with international or national quality standards. Declaration of Conformity Directive 93 | 42 | EEC, or other similar documents.	By apostill	Provided by the manufacturer
6	Technical file for a medical product, including consumables and accessories in accordance with the Order of 11 n.	Manufacturer's stamp and signature	Provided by the manufacturer, our company will analysis and adjustment in accordance with Russian requirements.
7	The instruction manual for the medical device, including consumables and accessories, in accordance with the Order 11 n.	Manufacturer's stamp and signature	Provided by the manufacturer, our company will analysis and adjustment in accordance with Russian requirements.
8	Risk management file.	Manufacturer's stamp and signature	Provided by the manufacturer
9	Photographic images of the general form of the medical device, along with the accessories necessary for using the medical device for its intended purpose (at least 18 x 24 cm in size).	Manufacturer's stamp and signature	Provided by the manufacturer
10	Reports on technical and clinical studies in the country of production.	Manufacturer's stamp and signature	Provided by the manufacturer
11	Information on the verification and validation of the medical device, if available (sterilization reports,	Manufacturer's stamp and signature	Provided by the manufacturer

	software validation reports, packaging process reports, accelerated aging report)		
12	Information about the samples that will be used during registration in the Russian Federation (name, model, country of origin, serial number, expiration date).		Provided by the manufacturer
13	Information on all raw materials (grade of raw materials, composition in% ratio, manufacturer, safety data sheets, MSDC).		Provided by the manufacturer

Note:

- ***It is necessary to provide translations of documents in accordance with the legislation of the country of manufacture.***

- ***Apostille certification occurs immediately before submission to Roszdravnadzor; at the stage of analysis and development, electronic documents are required.***