ЛЁГКИЕ ДОКУМЕНТЫ
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The documents required for registration of foreign medical product

The documents submitted to the Federal Service for Supervision in the Sphere of Health Care of the Russian Federation (Roszdravnadzor):

1 Technical File
2 Test Report
3 Electromagnetic Compatibility Test Report
4 Risk analysis
5 Clinical Report
6. Operational Documentation

The documents are certified with a seal, signature and notarization (and apostille) in the country of origin.

1	A copy of the document confirming the authority of the representative (manufacturer);
2	Information about the regulatory documentation for the medical product;
3	Technical documentation of the manufacturer;
4	Operational documentation of the manufacturer (s), including instructions for use or manual to the medical product;
5	Photographic general images of the medical product, along with the accessories necessary for the use of the medical product for its intended purpose (at least 18 x 24 centimeters in size);
6	Documents confirming the results of technical tests of the medical product;
7	Documents confirming the results of toxicological tests of the medical product, the use of which implies contact with the human body;
8	Documents confirming the test results of the medical product for the purpose of approving the type of measuring instruments (for medical products related to measuring instruments in the state regulation of ensuring the uniformity of measurements, the list of which is approved by the Ministry of Health of the Russian Federation);
9	Quality Management System Certificate ISO:13485 (notarization and apostille required)
10	Quality Management System Certificate ISO:9001 (notarization and apostille required)
11	CE Certificate, Free Trade Certificate, etc.(notarization and apostille required)
12	Information confirming the clinical efficacy and safety of the medical product (if available);
13	Draft program of clinical tests of the medical product with substantiating materials (if available)
14	List of documents

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