ЛЁГКИЕ ДОКУМЕНТЫ
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The documents required for registration of Russian medical product

1	Copies of a legal entity or sole proprietor registration documents: • Certificates of state registration of legal entities • Certificates of registration with a tax authority of a legal entity or a sole proprietor (or the corresponding entry sheets in the Unified State Register of Legal Entities or Sole Proprietors) • Extracts from the Unified State Register of Legal Entities or Sole Proprietors
2	Technical File
3	18x24 photos (in color in package and not, with all accessories)
4	A power of attorney for the representative of the manufacturer of the medical product (Russian company engaged in the registration of medical products)
5	Instructions for use the medical product
6	Risk Management File
7	Qualification Test Certificate
8	Information on the use of similar medical products in the Russian Federation (web links, brochures, etc.)
9	Technical and Toxicological Test Records
10	Software Validation and Verification Protocols (if necessary)
11	Sterilization Validation Protocol (if necessary)
12	Stability Report (if necessary)
13	ISO 13485 Certificate (if necessary)

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