THE PACKAGE OF DOCUMENTS FOR REGISTRATION OF MEDICAL DEVICE:

- A document confirming the registration of organization as a legal entity
(Business license or the extract from the commercial register of country of manufacturer) Apostille.

- **The document confirming powers of the authorized representative of the manufacturer:** POWER OF ATTORNEY (we will provide a template) Apostille.

- **For foreign manufacturers:**
- ✔ the documents confirming compliance **with the foreign production of international ISO standards (ISO 13485 certificate necessarily + report, ISO 9001 certificate in the presence of**) Apostille.
- ✔ the documents confirming compliance with the foreign production of international standards 93/42/EEC (**CE Certificate in the presence of**) Apostille.

-**The document governing the relationship between the developer and the manufacturer of the medical product** (if the developer and manufacturer of medical product are different legal entities).

-Technical documentation of the manufacturer (producer) for a medical product *for foreign manufacturers:*
- the technical file of the manufacturer[1] (Simplified Technical File) or a consolidated set of technical documentation (Summery technical documentation).

-The operational documentation of the manufacturer (producer) for a medical product, including instructions for use or user manual of a medical product

-Working drawings, tables and diagrams, if they are not contained in the operating documents.

-Documentation for the assembly and installation of the medical product

-Photographic images of a medical product general form with accessories required for the use of a medical device for the intended purpose (no smaller than 18x24 cm):
- represented a clear photographic images to uniquely identify the medical device and its accessories.

-Samples of labeling of the medical product made in accordance with the requirements of normative documents of the Russian Federation (for the labeling of the product of foreign production in Russian).
-Documents created by the manufacturer in the process of risk analysis of the application of MP containing information about the risks associated with MP, and the measures taken to reduce residual risk (**risk management file**).

-The results of the preliminary work in developing of the medical product:
- ✔ Reports on the conducted R & D;
- ✔ The reports on clinical trials.

-The draft plan of clinical trials of the medical product with supporting materials (if available):

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[1] The technical file is a document created by the manufacturer, where technical specifications are presented. If the product is presented as a product line, the technical file must contain a comparative table of technical characteristics of each model (design). This is a very large document which contains everything up to schemes of the product and the manufacturing process, some of the information is a commercial secret. Therefore, on the basis of this document an extract from the technical file is created with the required information for the registration.

presented (if available) for medical products of a potential risk classes 2A, 2B, 3.

- Information about the manufacturers of materials, the name of the material and the brand of material in contact with human skin (necessarily) and certificates of conformity of materials (in the presence of)

Initially, all the documentation mentioned above is provided only in electronic form!