



SCHEME OF

MEDICAL PRODUCTS STATE REGISTRATION

1 - Provision of the initial documentation set:

Documents provided by Manufacturer:

- The Power of Attorney for registration issued by the manufacturer for the applicant (Authorized Representative) or the Contract;
- The Manufacturer's Certificate of Incorporation;
- Certificate ISO 13485 and / or ISO 9001;
- EU Certificate and / or Declaration of Conformity 93/42/EEC;
- User Manual;
- Set of technical documentation;
- Test Reports;
- Clinical studies.

Documents provided by Applicant

(Authorized Representative in Russian Federation):

- Registration application
- Extract from the Unified State Register of Legal Entities
- Payment orders confirming payment of the state duties
- A set of accompanying documentation (to be prepared jointly with the Contractor)

2 - Providing samples for testing with a set of documentation on the importation of Medical Products

3 - Finalization of the manufacturer's documentation in compliance with requirements of the RF Legislation

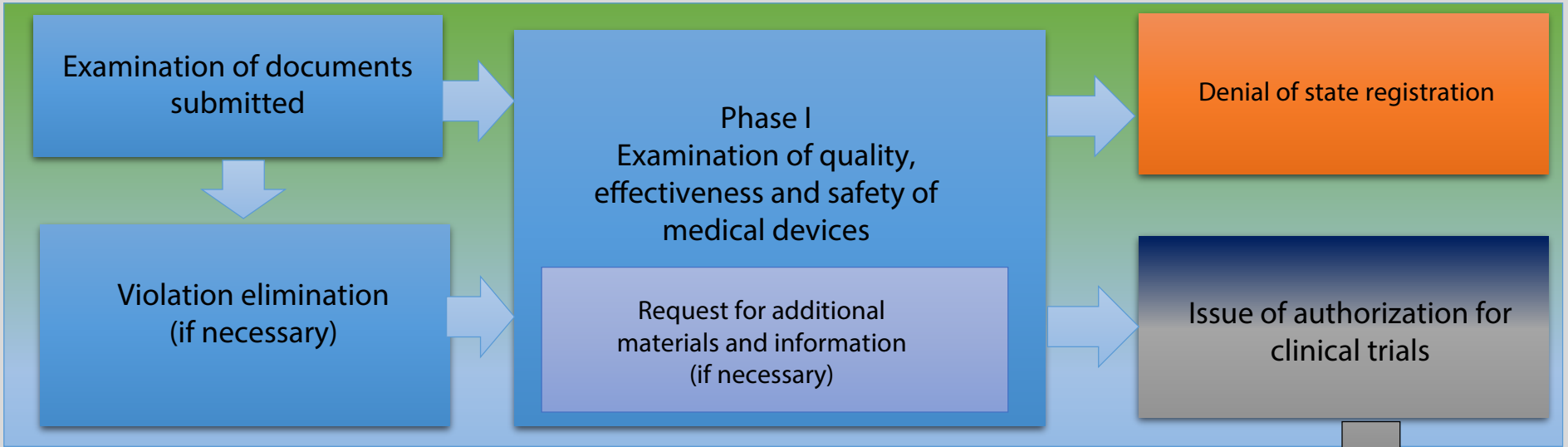
4 - Conducting tests of medical devices (resulting in Test Reports):

- ✓ Technical
- ✓ Electromagnetic compatibility (if necessary)
- ✓ Toxicological
- ✓ Implantation test (if necessary)
- ✓ In order to approve the type of measuring instruments (if necessary)
- ✓ Specific tests in vitro (if necessary)

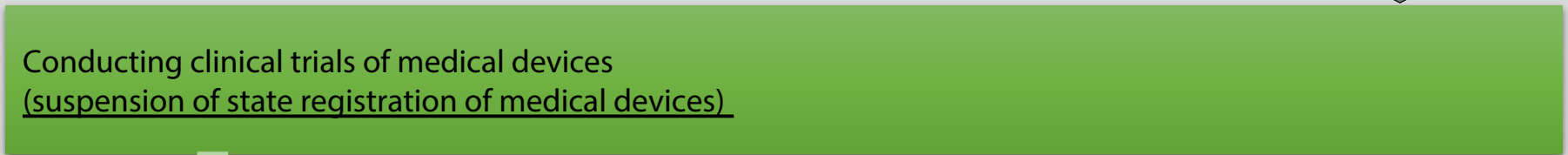
Preparation of documents
(Registration Dossier)
for submission



Registration Phase I



Preparation of Documents



Registration Phase II

