SCHEME OF

MEDICAL PRODUCTS STATE REGISTRATION

Preparation of documents (Registration Dossier) for submission

1 - Provision of the initial documentation set:

Documents provided by Manufacturer:	Documents provided by Applicant (Authorized Representative in Russian Federation):
-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.	- 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)

Registration Phase I

Examination of documents submitted

Violation elimination (if necessary)

Phase I
Examination of quality, effectiveness and safety of medical devices

Request for additional materials and information (if necessary)

Denial of state registration

Issue of authorization for clinical trials

Preparation of Documents

Conducting clinical trials of medical devices
(suspension of state registration of medical devices)

Registration Phase II

Renewal of state registration (submission of an clinical test report to Roszdravnadzor)

Examination of documents submitted

Phase II
Examination of quality, effectiveness and safety of medical devices

Request for additional materials and information (if necessary)

Denial of state registration

Issue of Registration Certificate