Attachment #4 to the Assessment process of conformity assessment in the form of technical testing, toxicological research, clinical trials, medical products for the purpose of state registration of medical devices

Requirements for technological and service documentation for a medical product

1) Technological documentation for a medical product must contain the following:
a) Product name
b) Information about the manufacturer — name (full and abbreviated company name), legal address, postal address, telephone of the legal entity or first, second and given name (if exists), residence address, postal address, private entrepreneur's telephone number, manufacturer's address.
c) Medical product designation, made by a manufacturer including
-indications — diseases or human conditions, which implies using this medical product for prevention, diagnosis, treatment of the diseases and rehabilitation, human condition monitoring, conducting medical researches, recovery, restoration, changing the anatomical organization or physiological function, prevention of pregnancy or abortion.
-contraindications
-method of administration
-conditions of use of the medical product in medical establishment, in a vehicle, in the field or home environment, for general or individual administration;
d) Classification of the medical product:
-All-Russian Classification of Products code for medical product (OKP code);
-Category, according to the potential risk of the usage of product, according to the Nomenclature Classification of Medical Devices by Type
-Type of the product, according to the Nomenclature Classification of Medical Devices by Type
-Electrical safety class, laser safety class, and other hazards (if exists);
-Type of contact with the human body;
e) Description of principles which include the work of the medical product and special aspects
f) technical description of the medical product (build and appearance, photo or image, ingredients, implements and components list, chemical composition in vitro, general chart (scheme), possibility and means of integration with other medical products, materials, which form the medical product or it's basic parts (it is necessary to name materials, which directly contact with the human body), information about marking, package etc.);
g) the main parameters and characteristics of the medical product (standardized specifications and analytical characteristics of the products for the diagnosis in vitro, lifetime, expiration date);
h) safety requirements (including methods and remedies);
i) requirements for the environment protection in the application of the medical device;
g) test and control methods;
k) methods and means of disinfection and presterilizing clearing;
l) sterilization methods and conditions, terms of maintaining sterility (for sterile manufactured medical products);
m) a list of national and international regulations / standards, which correspond to the medical device;
o) Operating conditions:
-requirements for assembly and installation;
-maintenance information;
-information verification (for medical devices to be allocated to the measuring instruments in the field of state regulation of assurance of measurement);
p) transportation and storage conditions;
q) warranty liabilities;
r) the list of equipment and measuring devices required for quality control of medical products;

All of the information in the technical documentation must be confirmed by relevant documents of the manufacturer.

2) User documentation for the medical device, including the instructions for use or operating instructions of the medical product must contain the following information:

a) The name of the medical product;
b) Application field;
c) Indications for use of the medical product
d) Contraindications for the use of the medical device
e) Precautions for use of the medical device
f) Possible side affects of using medical product;
g) Interaction with other medical products;
h) Indication of the possibilities and characteristics of the application of the medical product for people with implanted into the human body medical devices, pregnant women, lactating women, children, adults with chronic diseases;
i) Information about the possible impact of the use of a medical product on the ability to drive vehicles, operate machinery;
j) Lifetime and an indication of the ban on the use of a medical device at the expiry date;
k) Storage conditions;
l) Indication of the necessity for storage of medical products out of the reach of children;
m) Indication of any special precautions for the destruction of unused medical products (if they exist);
n) Information about the manufacturer — name (full and abbreviated company name), legal address, postal address, telephone of the legal entity or first, second and given name (if exists), residence address, postal address, private entrepreneur's telephone number, manufacturer's address;
o) Configuration types of the medical product;
p) Technical specifications, the general scheme of the product, characteristics of used consumables (as applicable).
q) Requirements for the application and operation of the medical device;
r) Requirements for the maintenance and repair of medical product, for the personnel, including a list of recommended hardware, equipment and measuring instruments, as well as the frequency of maintenance and repairs (if necessary).
s) The procedure of disposal and destruction.