Ref no \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

From "\_\_\_" of \_\_\_\_\_\_\_\_\_\_ 2015

To the President of the Association

"RUSSIAN DENTAL INDUSTRY"

Pavel Dobrovolskiy

Application

In accordance with the contract No. XXXX/2015 from XX.XX.2015 I ask to render the following services:

- To make an assessment of the completeness and conformance of the documents prepared by the manufacturer (producer) to the requirements of the registration file of Federal Supervision Service for Health Care and Social Development (hereinafter Roszdravnadzor);

- To make an assessment of the completeness and conformance of the obtained results of laboratory researches (reports of technical tests carried out by certified test laboratory) to the requirements of the registration file of Roszdravnadzor;

- To carry out laboratory researches in accredited test laboratories (biomedical tests), including the payment of these researches, certifying true copies of documents, signature and performance of all other actions related to the carrying out researches and obtaining test reports;

- To compile the file for submission to Roszdravnadzor, to submit the file in Roszdravnadzor and obtain the reference number on the document review status in Roszdravnadzor;

- To get the referral from Roszdravnadzor on carrying out expert examination of quality, efficiency and reliability (examination of the first stage documents);

- To compile the file for carrying out the examination of the first stage documentation in accredited organizations and to obtain the expert opinion on the possibility / impossibility of carrying out clinical tests;

- To carry out clinical tests in the accredited medical organizations and to obtain test reports;

- To get the referral from Roszdravnadzor on carrying out expert examination of quality, efficiency and reliability (examination of the second stage documents);

- To compile the file for carrying out the examination of the second stage documentation in accredited organizations and to obtain the expert opinion on the possibility / impossibility of obtaining the registration certificate;

- To compile the registration file and to obtain the Roszdravnadzor registration certificate;

- To carry out obligatory declaring in the accredited certification agency and to obtain the declaration of conformity for our products:

«...»

Developer:

*Full and (in case is available) the abbreviated name, including a trade name, an organizational and legal form of the legal entity, the address of its location, and also phone numbers and (in case is available) the e-mail address of the legal entity*

Manufacturer:

*Full and (in case is available) the abbreviated name, including a trade name, an organizational and legal form of the legal entity, the address of its location, and also phone numbers and (in case is available) the e-mail address of the legal entity*

Authorized representative of the manufacturer:

*Full and (in case is available) the abbreviated name, including a trade name, an organizational and legal form of the legal entity, the address of its location, and also phone numbers and (in case is available) the e-mail address of the legal entity*

Recipient of the registration certificate:

*Full and (in case is available) the abbreviated name, including a trade name, an organizational and legal form of the legal entity, the address of its location, and also phone numbers and (in case is available) the e-mail address of the legal entity*

Addresses of the places of medical product manufacture:

*If the medical product is made by one producer and the address of place of production coincides with the legal address, the legal address is specified.*

Intended use of the medical product specified by the manufacturer:

*Appointment and the scope of a medical product established by the producer is specified.*

Type of the medical product according to the nomenclature classification of medical products:

*Classification needs to be carried out according to the Order of the Russian Ministry of Health of 06.06.2012 No. 4n "About the adoption of nomenclature classification of medical products".*

Information on the medical product and its accessories:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Item | Name of product | Material | Contact with human body | Quantity of samples | Type of sterilization |
| 1 | 2 | 3 | 4 | 5 | 6 |
|  |  |  |  |  |  |

Photographic images of the product:

CEO \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Full Name

Place of Signature