

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

DQS has issued an IQNet recognized certificate that the organization

Federal State Institution "State Institute of Drugs and Good Practices"

Lavrov lane, 6, building 5 109044, Moscow Russian Federation

with the organizational units/sites as listed in the annex

has implemented and maintains a Quality Management System.

for the following scope:

Implementation of applied scientific research in the field of pharmacology and biotechnology, in terms of the development of pharmaceutical substances, drugs and medical devices, study of the mechanisms of drugs action on the body of animals and humans, inspection of drug manufacturers for compliance with the requirements of good manufacturing practice, provision of medical services to the attached contingent

which fulfills the requirements of the following standard:

ISO 9001: 2015

Issued on: 2020-12-17 Expires on: 2023-12-16

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.

Registration number: DE-31102041 QM15



Alex Stoichitoiu President of IQNet



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SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

^{*} The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



Annex to IQNet Certificate Number: 31102041 QM15

Federal State Institution "State Institute of Drugs and Good Practices"

Lavrov lane, 6, building 5 109044, Moscow Russian Federation

Location Scope

31102150
Branch of Federal State Institution "State Institute of Drugs and Good Practices" – Medical Unit
Bolshoy Afanasievskiy lane, 11-13
109019, Moscow
Russian Federation

Carrying out medical activities



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Detailed scope:

- organization and conduction Good Manufacturing Practices (GMP) inspections of pharmaceutical production sites to ensure their compliance with the GMP requirements;
- organization and holding of Russian and International scientific workshops and medical seminars, conferences, symposia;
- information and consulting services;
- research and development of new medicines, improvement of existing medicines;
 chemical-analytical studies, including studying the stability of the drug and establishing
 the shelf life; pharmacopeia draft articles, technological regulations, analytical methods,
 norms and standards development; development and production of laboratory samples of
 medicines for pre-clinical studies;
- carrying out of analytical researches in the pharmaceutical and medical industries;
- analytical research into the pharmaceutical and medical industry; design qualification and review; clean rooms, engineering systems and equipment qualification for compliance with the GMP requirements;
- implementation of information interaction in the collection, processing and analysis of production capacities data, production lines and manufactured products as part of the work of manufacturers in the drug movement monitoring system;
- carrying out medical activities