CERTIFICATE

This is to certify that

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

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

has implemented and maintains a **Quality Management System**.

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 assigned contingent

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	31102041 QM15
Date of revision	2021-12-22
Valid from	2020-12-17
Valid until	2023-12-16
Date of certification	2021-12-22

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16074-01-00

DQS GmbH

Markus Bleher
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Annex to certificate
Registration No. 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

This annex (edition: 2021-12-22) is only valid in connection with the above-mentioned certificate.

Annex to certificate
Registration No. 31102041 QM15

Federal State Institution
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Detailed scope:

- organization and conducting Good Manufacturing Practices (GMP) inspections of pharmaceutical production sites for compliance with the GMP requirements;
- organization and holding of Russian and International scientific workshops and medical seminars, conferences, symposia;
- providing 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 monographs, master production record, analytical methods, regulations and standards development; development and production of laboratory samples of medicines for organization of conducting of pre-clinical studies; organization of conducting of clinical studies of medicines;
- pharmaceutical and medical industry analytical research; carrying out expert examination of scientific and scientific and technology programmes and projects; design qualification and review; clean rooms, utility 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;
- evaluation and expertise of pharmaceutical projects