

CERTIFICATE

This is to certify that the Quality Management System of
Republican state enterprise on the right of economic
management "National Center for Expertise of Medicines
and Medical Devices" of the Committee for Quality Control
and Safety of Goods and Services of the Ministry
of Health of the Republic of Kazakhstan

Legal address: 20, Mangilik Elm Ave., 010000, Yesil district, Nur-Sultan, , Republic of Kazakhstan Actual address: 2/3, Bauyrzhan Momyshuly Ave., 010000, Almaty district, Nur-Sultan, ,Republic of Kazakhstan

has been assessed and found to be in accordance with the requirements of

ISO 9001:2015

in respect of health care activities related to the state monopoly (examination during state registration, reregistration and amendments to the registration dossier of medicines and medical devices, safety and quality assessment of medicines and medical devices registered in the Republic of Kazakhstan), and also activities technologically related to the state monopoly in area health care

No: 19.2508.026

of 24th December, 2019

This certificate is valid until 24th December, 2022

Director General of Certification Association "Russian Register"

Specification of the certification scope is provided in Annex. This certificate becomes invalid if conditions of certification are not fulfilled (http://www.rusregister.ru/doc/004.00-105.pdf). This Certificate is the property of Certification Association "Russian Register".









LIST OF THE COUNTRIES WHICH ARE REPRESENTED IN IAF AND ARE SIGNATORIES OF THE MULTILATERAL AGREEMENT ON RECOGNITION IAF MLA*:

Australia and New Zeeland JAS-ANZ, Argentina OAA, Austria AA, Belgium BELAC, Bulgaria EA-BAS, Brazil CGCRE, Great Britain UKAS, Hungary NAH, Vietnam BoA, Germany DAkkS, Hong-Kong HKAS, Greece ESYD, Denmark DANAK, Egypt EGAC, India NABCB, Indonesia KAN, Iran NACI, Ireland INAB, Spain ENAC, Italy ACCREDIA, Kazakhstan NCA, Canada SCC, China CNAS, Colombia ONAC, Korea KAB, Costa Rica ECA, Luxemburg OLAS, Malaysia DSM, Mexico EMA, Netherlands RvA, Norway NA, UAE DAC, ARAC Pakistan PNAC, Peru INACAL-DA, Poland PCA, Portugal IPAC, Rumania RENAR, Serbia ATS, Singapore SAC, Slovakia SNAS, Slovenia SA, USA ANAB, IAS, Thailand NSC, Taiwan TAF, Tunisia TUNAC, Turkey TURKAK, Ukraine NAAU, Uruguay OUA, Philippines PAB, Finland FINAS, France COFRAC, Czech Republic CAI, Chile INN, Switzerland SAS, Sweden SWEDAC, Sri-Lanka SLAB, Ecuador SAE, South Africa SANAS, Japan JAB * List of MLA signatory IAF members may change. Current list of MLA IAF member accreditation bodies is available on IAF website: www.iaf.nu

CИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА RUSSIAN REGISTER CERTIFICATION SYSTEM



Annex to the Certificate Nº 19.2508.026 of 24th December, 2019 registration form Nº 01-013997

Certification scope of management system of Republican state enterprise on the right of economic management "National Center for Expertise of Medicines and Medical Devices" of the Committee for Quality Control and Safety of Goods and Services of the Ministry of Health of the Republic of Kazakhstan

- 1. Product / service: health care activities related to the state monopoly (examination during state registration, re-registration and amendments to the registration dossier of medicines and medical devices, safety and quality assessment of medicines and medical devices registered in the Republic of Kazakhstan), and also activities technologically related to the state monopoly in area health care.
- 2. The requirements of p. 8.3 ISO 9001:2015 are not applicable to the certification scope of QMS.

Director General of Certification Association "Russian Register" REGISTALINE WAY

A. Vladimirtsev

CИСТЕМА СЕРТИФИКАЦИИ РУССКОГО РЕГИСТРА RUSSIAN REGISTER CERTIFICATION SYSTEM



Annex to the Certificate Nº 19.2508.026 of 24th December, 2019 registration form Nº 01-013997

Certification scope of management system of Republican state enterprise on the right of economic management "National Center for Expertise of Medicines and Medical Devices" of the Committee for Quality Control and Safety of Goods and Services of the Ministry of Health of the Republic of Kazakhstan includes:

1. Laboratory Testing Center

53/11, Kabanbay Batyra Ave., block 53 (S4), 010017, Nur-Sultan, Republic of Kazakhstan

2. Territorial branch in the city of Almaty

63, Abylay Khana Str., 050000, Almaty, Republic of Kazakhstan

3. Testing center with laboratories of Almaty territorial branch 40A, Bayturcynova Str., 050000, Almaty, Republic of Kazakhstan

4. Territorial branch in the city of Karaganda9A, Bukhar Zhyrau Ave., 100000, Karagandy, Republic of Kazakhstan

5. Territorial branch in the city of Aktobe 19A, Gertsena Str., 030000, Aktobe, Republic of Kazakhstan

6. Territorial branch in the city of Ust-Kamenogorsk 29, Belinsky Str., 070000, Ust-Kamenogorsk, Republic of Kazakhstan

7. Territorial branch in the city of Taraz 42, Kosheny Str., 080014, Taraz, Republic of Kazakhstan

8. Representation in the city of Shymkent46/43, Tamerlanovskaya track, 160000, Abay district, Shymkent, Republic of Kazakhstan

9. Representation in the city of Pavlodar 91, Lermontova Str., 140000, Pavlodar, Republic of Kazakhstan

10. Representation in the city of KostanayLeonida Bedy Str., 23A, 110000, Kostanay, Republic of Kazakhstan

Director General of Certification Association "Russian Register" A. Vladimirtsev