

G-CERTI *certificate*

hereby certifies that

«DNA-Technology Research& Production», LLC

Site 1: “DNA-Technology Research&Production”, LLC, 142281, Russia, Moscow region, city district Serpukhov, Protvino, Zheleznodorozhnaya street, 20

Site 2: “DNA-Technology Research&Production”, LLC, 142281, Russia,

Moscow region, city district Serpukhov, Protvino, Zheleznodorozhnaya street, 3

Site 3: “DNA-Technology TS”, LLC, 117246, Russia, Moscow, proezd Nauchny, 20, building 4

Site 4: “DNA-Technology TS” LLC, 117587, Russia, Moscow, int. ter. Municipal District Chertanovo Severnoye, Varshavskoye shosse, 125 Zh, building 7

Site 5: “DNA-Technology” LLC, 117587, Russia, Moscow, int. ter. Municipal District Chertanovo Severnoye, Varshavskoye shosse, 125 Zh, building 5, floor 1, office 12

Site 6: “DNA-Technology Research&Development”, LLC, 117587, Russia, Moscow, int. ter. Municipal District Chertanovo Severnoye, Varshavskoye shosse, 125 Zh, building 7

meets the Standard Requirements & Scope as following

ISO 13485:2016 Medical Devices--Quality Management Systems

Design, manufacturing and distribution of in-vitro diagnostic reagents and devices for medical molecular-genetic diagnostics.

Certificate No : GKRST-0002-MD	Code : D
Initial Date : 2023. 01. 24	Issue Date : 2025. 11. 12
Expiry Date : 2029. 01. 23	Valid Period : 2026. 01. 24 ~ 2027. 01. 23

*Signed for and on behalf of GCERTI
President I.K.Choi*



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«DNA-Technology Research& Production», LLC

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Site 6: “DNA-Technology Research&Development”, LLC, 117587, Russia, Moscow, int. ter. Municipal District Chertanovo Severnoye, Varshavskoye shosse, 125 Zh, building 7

meets the Standard Requirements & Scope as following

ISO 9001:2015 Quality Management Systems

Design, manufacturing, sales, marketing and distribution of in-vitro diagnostic reagents and devices for molecular-genetic diagnostics and other laboratory use.

Certificate No : GKRST-0002-QC	Code : 12, 23
Initial Date : 2023. 01. 24	Issue Date : 2025. 11. 12
Expiry Date : 2029. 01. 23	Valid Period : 2026. 01. 24 ~ 2027. 01. 23

Signed for and on behalf of GCERTI
President I.K.Choi



**<G-CERTI> is accredited by IAS member of IAF
for the scope and sub scopes described in this certificate.**



To verify the validity of this certificate please visit : www.gcerti.com
Korea, Seoul, Eunpyeong-gu, Eunpyeong-ro, 88, 15F. Surveillance audits shall be conducted at least once a calendar year, except in recertification years. This is to certify that the Management Systems of this company has been found to confirm to the above. If the certified client does not allow surveillance, recertification audits, certificate should be returned to GCERTI. This certificate remains the property of GCERTI and this certificate is recognized by GCERTI.





MINISTÉRIO DA SAÚDE

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

CERTIFICADO DE BOAS PRÁTICAS DE FABRICAÇÃO E CONTROLE DE PRODUTOS PARA SAÚDE

Considerando o disposto na Lei n.º 9.782, de 26 de janeiro de 1999, o Decreto nº 3.029, de 16 de abril de 1999 e a publicação no Diário Oficial da União por meio da Resolução RE nº **1.199** na data de **30/03/2026** certifico que a empresa, a seguir descrita, cumpre com a legislação sanitária vigente, quanto às Boas Práticas de Fabricação de produtos para saúde exigidas pela autoridade sanitária brasileira, estando sujeita a inspeções periódicas.

Fabricante: DNA-Technology TS LLC.

Endereço: Nauchnyi Proyezd, 20, Bld 4, Moscou, 117246 - Rússia

Solicitante: GeneStar Inovações e Equipamentos Médicos Ltda. CNPJ: 35489323/0001-75

Autorização de Funcionamento: 8214992 Expediente: 0142113/26-3

Certificado de Boas Práticas de Fabricação de Produtos para Saúde.

Produtos para diagnóstico de uso in vitro das classes III e IV.

Motivo: Subsidiado por relatório de inspeção, requisito necessário para decisão do ato.

Validade até: 30/03/2028



Documento assinado eletronicamente por **Renata de Lima Soares, Gerente-Geral de Inspeção e Fiscalização Sanitária**, em 07/04/2026, às 14:56, conforme horário oficial de Brasília, com fundamento no § 3º do art. 4º do Decreto nº 10.543, de 13 de novembro de 2020 http://www.planalto.gov.br/ccivil_03/_ato2019-2022/2020/decreto/D10543.htm.



A autenticidade deste documento pode ser conferida no site <https://sei.anvisa.gov.br/autenticidade>, informando o código verificador **4168636** e o código CRC **14AAB41F**.



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Reg. No. 575/Q-074

Certification body of management systems

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Studentska 12, 911 01

Trencin | Slovakia

www.bqsgroup.eu

Certificate QMM 23 020 0159 rev.01

Quality management system certification

Certificate holder: **DNA-Technology, Research & Production, LLC.**
Zheleznodorozhnaya street, 20,
Moscow region, Urban District Serpukhov,
Protvino, 142281, Russia

Applied standard: **EN ISO 13485:2016**

Related audit report: AQMM 2023CB020 S02



Other Facility(ies):

DNA-Technology TS, LLC, Nauchnyi proyezd, 20, bld.4., Moscow 117246, Russia

DNA-Technology, Research & Production, LLC., Zheleznodorozhnaya street 3, Moscow region, Urban District Serpukhov, Protvino, 142281, Russia

DNA-Technology, LLC., Varshavskoye shosse, 125 Zh, building 5, floor 1, office 12, int. ter. Municipal District Chertanovo Severnoye, Moscow 117587, Russia

DNA Technology R&D, LLC, Varshavskoye shosse, 125 Zh, building 7, int. ter. Municipal District Chertanovo Severnoye, 117587, Moscow, Russia

The certificate was issued with respect to the following scope:

Design, manufacturing and distribution of in-vitro diagnostic reagents and devices for medical molecular-genetic diagnostics.

This certificate is effective from 10th February 2026 until 16th June 2027 and remains valid subject to execution surveillance audits and continuous compliance.

Initial version of the certificate was effective from 17th June 2024.

Certification has been authorized by

Radovan Macaj
Head of Certification body

bqs.

Certified management system

bqs issued the certificate on the basis of performed audit and assessment of the quality management system in accordance with the harmonised standard EN ISO 13485:2016 and according to the requirements for certification bodies providing audit and certification of management systems, laid down by ISO/IEC 17021-1:2015. The certified quality management system is subjected to periodical surveillance performed by bqs. Please see also notes overleaf if any.



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Certificate QMS 23 021 0160 rev. 01

Quality management system certification

Certificate holder: **DNA-Technology, Research & Production, LLC.**
Zheleznodorozhnaya street, 20,
Moscow region, Urban District Serpukhov,
Protvino, 142281, Russia

Applied standard: **EN ISO 9001:2015**

Related audit report: AQMS 2023CB021 S01



Other Facility(ies): DNA-Technology TS, LLC, Nauchnyi proyezd, 20, bld.4., Moscow 117246, Russia
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