

G-CERTI *certificate*

hereby certifies that

«DNA-Technology Research& Production», LLC

142281, Russia, Moscow region, Protvino, Zheleznodorozhnaya street, 20.

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

Site 2: "DNA-Technology TS", LLC, 117246, Russia, Moscow, proezd Nauchny, 20, building 4.

Site 3: "DNA-Technology Research&Development", LLC, 109388, Russia, Moscow, Guryanova street, 83, building 1.

Site 4: "DNA-Technology Research&Production", LLC, 142281, Russia, Moscow region, Protvino, Zheleznodorozhnaya street, 3.

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 : 2023. 10. 19

Expiry Date : 2026. 01. 23 Valid Period : 2023. 10. 19 ~ 2025. 01. 23

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



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 conform 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.





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Certification body of management systems

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Certificate QMM 23 020 0159

Quality management system certification

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

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

Related audit report: AQMM 2023CB020 I01



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, 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., Gurianova street, 83, bld.1, Moscow 109388, Russia

DNA-Technology, Research & Production, LLC., Zheleznodorozhnaya street 20, Moscow region, Protvino 142281, 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 17 June 2024 until 16 June 2027 and remains valid subject to execution surveillance audits and continuous compliance.

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.