

# 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](http://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.



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*meets the Standard Requirements & Scope as following*

## **ISO 9001:2015** **Quality Management Systems**

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

Certificate No : GKRST-0002-QC Code : 12, 23  
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



**<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](http://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.







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Certification body of management systems

bqs. s.r.o.  
Studentska 12, 911 01  
Trencin | Slovakia  
www.bqsgroup.eu

## 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.





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Trencin | Slovakia  
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## Certificate QMS 23 021 0160

Quality management system certification

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

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

**Related audit report:** AQMS 2023CB021 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, sales, marketing and distribution of in-vitro diagnostic reagents and devices for molecular-genetic diagnostics and other laboratory use.**

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 9001:2015 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.