



# Certificate

No. Q5 075098 0005 Rev. 00

**Holder of Certificate:** **Macrogen Inc.**  
10F, 11F, 254, Beotkkot-ro, Geumcheon-gu  
Seoul 08511  
REPUBLIC OF KOREA

**Certification Mark:**



**Scope of Certificate:** **Design, Development, Production and Distribution of in vitro diagnostic kit for Real-time PCR used in the detection of infectious diseases**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 075098 0005 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5 075098 0005 Rev. 00)

**Report No.:** 74958535

**Valid from:** 2021-06-04  
**Valid until:** 2024-06-03

**Date,** 2021-06-04



Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** Macrogen Inc.  
10F, 11F, 254, Beotkkot-ro, Geumcheon-gu, Seoul 08511,  
REPUBLIC OF KOREA

See Scope of Certificate

**Parameters:**