



Management System Certification Body No. MSCB-105

# CERTIFICATE

No. 23-B-1587 Rev. 0

**GeneCker Co., Ltd.**

#1006,1007, HausD SeJong Tower, 26, Seongsuil-ro 10-gil, Seongdong-gu,  
Seoul 04793 REPUBLIC OF KOREA

Company Reg. No.: 414-81-06667

has documented and implemented system in compliance with the requirements of

**ISO 13485:2016**

**Medical Devices Quality Management System**

for

**Development, Manufacture and Sales of  
molecular diagnostic reagent for In Vitro Diagnostics Use.**

**Technical Area:**

**C: In Vitro Diagnostic Medical Devices (IVD) - Reagents and reagent products,  
calibrators and control materials for Genetic Testing**

The certificate is issued on the basis of the results mentioned in the pertinent audit report.  
Validity of the certificate is conditionally limited by positive results of surveillance audits,  
which the certified company is committed to undergo.

This certificate can be invalid if the certificate holder does not fulfill the conditions set out in  
the certification agreement.

Initial issue date: Apr. 11. 2023

Expire date: Apr. 10. 2026



*G. Gilbert*

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Head of Certification Body

