

# CERTIFICATE

No. 22-B-1410 Rev. 0

**LabTech Ready GmbH**

Schellingstr. 109a D-80798 München, Germany

Company Reg. No.: HRB 252758

has documented and implemented system in compliance with the requirements of

**ISO 13485:2016**

**Medical Devices Quality Management System**

for

**Design, Development, Manufacturing and Sales of COVID-19 and Drug of Abuse Rapid Test Kits including: COVID-19 Antigen, COVID-19 IgG/IgM Antibodies, COVID-19 Neutralizing Antibody, Morphine, Amphetamine and Methamphetamine.**  
**Design, Development, Manufacturing and Sales of In Vitro (IVD) Diagnostic Including: Lateral Flow Immunoassay, ELISA, CLIA, Biochemistry and Coagulation.**

**Technical Area:**

C: In Vitro Diagnostic Medical Devices (IVD)

- Reagents and reagent products, calibrators and control materials for Immunochemistry (Immunology)
- Reagents and reagent products, calibrators and control materials for Haematology/Haemostasis/ Immunohematology
- Reagents and reagent products, calibrators and control materials for Infectious Immunology
- In Vitro Diagnostic Instruments and software

F: Parts or services - Distribution services

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: Aug. 05. 2022

Expire date: Aug. 04. 2025



*G. Gilbert*

G. Gilbert

Head of Certification Body

