



Management System Certification Body No. MSCB-105

# CERTIFICATE

No. 22-B-1311 Rev. 2

## VITROSENS BİYOTEKNOLOJİ ANONİM ŞİRKETİ

Şerifali Mah. Şehit Sk. No:17/A Ümraniye İstanbul TÜRKİYE

Company Reg. No.: 9251175360

has documented and implemented system in compliance with the requirements of

**ISO 13485:2016**

**Medical Devices Quality Management System**

for

**RESEARCH AND DEVELOPMENT, PRODUCTION, MARKETING, EXPORT AND IMPORT SERVICES OF IN-VITRO DIAGNOSTIC (DIAGNOSIS) PRODUCTS (TEST KITS FOR CLINICAL CHEMISTRY, IMMUNOLOGY, HAEMATOLOGY, IMMUNOHEMATOLOGY, MICROBIOLOGY, INFECTIOUS IMMUNOLOGY, HISTOLOGY, CYTOLOGY, GENETIC TESTING)**

**Technical Area:**

C: In Vitro Diagnostic Medical Devices (IVD)

- Reagents and reagent products, calibrators and control materials for Clinical Chemistry
- 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 Microbiology
- Reagents and reagent products, calibrators and control materials for Infectious Immunology
- Reagents and reagent products, calibrators and control materials for Histology/Cytology
- Reagents and reagent products, calibrators and control materials for Genetic Testing
- 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: Mar. 25. 2022

Re-issue date: May. 17. 2023

Expire date: Mar. 24. 2025



*G. Gilbert*  
G. Gilbert

Head of Certification Body

