

Certificate CN24/00007236

The management system of

Vitrosens Biotechnology Inc.

No:17/A, Sehit Street, Serifali District, Istanbul, 34775, Turkey

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and manufacture of in-vitro diagnostic test kits used in the diagnosis and detection of infectious disease testing, fertility testing, pregnancy testing, drugs of abuse, tumor markers, cardiac markers, diabetes markers, inflammation markers, coagulation and hormones, including professional use, home use/self-testing and near patient/point of care in-vitro diagnostic medical devices

This certificate is valid from 14 November 2024 until 14 November 2027 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 14 November 2024

Certified activities performed by additional sites are listed on subsequent pages.

L. Moran

Authorised by

Liz Moran
Business Manager

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Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
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Certificate CN24/00007236, continued

Vitrosens Biotechnology Inc.

SGS

ISO 13485:2016

EN ISO 13485:2016

Issue 1

Sites

Vitrosens Biotechnology Inc.

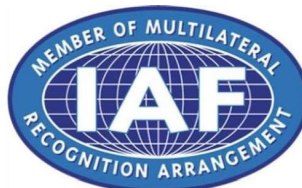
No:17/A, Sehit Street, Serifali District, Istanbul, 34775, Turkey

Design of in-vitro diagnostic test kits used in the diagnosis and detection of infectious disease testing, fertility testing, pregnancy testing, drugs of abuse, tumor markers, cardiac markers, diabetes markers, inflammation markers, coagulation and hormones, including professional use, home use/self-testing and near patient/point of care in-vitro diagnostic medical devices

Vitrosens Biotechnology Inc.

No:254, Ataturk Street, Merve District, Istanbul, 34791, Turkey

Manufacture of in-vitro diagnostic test kits used in the diagnosis and detection of infectious disease testing, fertility testing, pregnancy testing, drugs of abuse, tumor markers, cardiac markers, diabetes markers, inflammation markers, coagulation and hormones, including professional use, home use/self-testing and near patient/point of care in-vitro diagnostic medical devices



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