

CERTIFICATE



CERTIFICATE

EC Certificate No. 1434-IVDD-492/2021
EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies
that manufactured by:

Xiamen Wiz Biotech Co., Ltd.,
3-4 Floor, NO.16 Building, Bio-medical Workshop,
2030 Wengjiao Xi Road, Haicang District, Xiamen City,
Fujian Province, 361026, P.R. China

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)
51332801, 51332802, 51332803, 51332804

In terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 22.11.2021 to 27.05.2024

The date of issue of the Certificate: 22.11.2021

The date of the first issue of the Certificate: 22.11.2021



Issued under the Contract No. MD-77/2021
Application No: 130/2021
Certificate bears the qualified signature,
Warsaw, 22/11/2021
Module A1

Vice-President

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

Certificate C01192111

SGS

The management system of
Xiamen Wiz Biotech Co., Ltd.
3-4 Floor, NO. 16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road,
Haicang District, Xiamen City, Fujian Province, 361026, P.R. China

The full content is certified according to the requirements of
ISO 13485:2016
EN ISO 13485:2016

For the following activities:
The scope of registration appears on page 2 of this certificate.

This certificate is valid from 20 August 2020 until 3 September 2022
and remains valid subject to satisfactory surveillance audits.
The verification audit due before 20 July 2022
Issue 2, Certified since 8 September 2018

This is a multi-site verification.
Additional site details are listed on the subsequent page.

Authorized by

SGS under license to
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Certificate C01192111, continued

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Xiamen Wiz Biotech Co., Ltd.

ISO 13485:2016
EN ISO 13485:2016

Issue 2

Design and manufacture of *in vitro* diagnostic medical devices
including boronemia marker test kit, kidney disease marker test kit,
liver marker test kit, infectious disease marker test kit,
gastrointestinal inflammation marker test kit, cardiac marker test kit,
immunochromatography analyzer.

Address location
3 Floor, NO. 16 Building, Bio-medical Workshop, 2030 Wengjiao Xi Road,
Haicang District, Xiamen City, Fujian Province, 361026, P.R. China

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