

EC Certificate No. 1434-IVDD-478/2021

EC Design-examination
Directive 98/79/EC concerning
in vitro diagnostic medical devices

Polish Centre for Testing and Certification certifies that manufactured by:

VivaChek Biotech (Hangzhou) Co., Ltd. Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China

in vitro diagnostic medical devices for self-testing

The list of medical devices covered by this certificate is provided in the annex I

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 27.10.2021 to 27.05.2024

The date of issue of the Certificate: 27.10.2021

The date of the first issue of the Certificate: 27.05.2021

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Issued under the Contract No. MD-91/2021 Application No: 146/2021 Certificate bears the qualified signature. Warsaw, 27/10/2021 Module A1 Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba Data: 2021.10.27 15:13:37 +02'00'

Vice-President Mgr. Anna Wyroba