



CERTIFICATE

EC Certificate No. 1434-IVDD-460/2021

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

Polish Centre for Testing and Certification certifies
that manufactured by:

**Safecare Biotech (Hangzhou) Co., Ltd
311121 Hangzhou, Building 2/203, No. 18 Haishu
Rd.Cangqian Subdistrict, Yuhang District, China**

**in vitro diagnostic medical devices
for self-testing**

COVID-19 Antigen Rapid Test Kit (Swab)

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 23.09.2021 to 27.05.2024

The date of issue of the Certificate: 23.09.2021

The date of the first issue of the Certificate: 23.09.2021



Issued under the Contract No. MD-117/2021
Application No: 218/2021
Certificate bears the qualified signature.
Warsaw, 23.09.2021
Module A1

Vice-President



POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

BM.433.0218.2021.KW.MV.2024.0184

Warsaw, 22.03.2024

To Whom It May Concern,

Polish Centre for Testing and Certification informs about the change introduced to the EC Certificate no. **1434-IVDD-460/2021** issued for Safecare Biotech (Hangzhou) Co., Ltd, 311121 Hangzhou, Building 2/203, No. 18 Haishu Rd.Cangqian Subdistrict, Yuhang District, China, which results from the five-year certification period in accordance with Art. 9 section 10 of the Directive 98/79/EC, in force at the time the certificate was issued.

The EC Certificate validity date has been updated to **22 September 2026**.

Implementation of the change does not represent a significant change in design or intended purpose under Regulation (EU) 2017/746 Article 110(3) and the related IVDD Certificate no. 1434-IVDD-460/2021 issued 23 September 2021 remains valid until its expiry date or 26 May 2025, whichever comes first.

Yours Sincerely,

**Head of Medical Device
Certification Department**



CERTIFICATION.
TESTING.
TRAINING.

Polish Centre for Testing and Certification
469 Puławska Street, 02-844 Warsaw
Tel.: +48 22 46 45 200
pcbc@pcbc.gov.pl

NIP 9512063356
REGON 015276609
KRS 0000144813

Initial capital
16.000.000 PLN
(fully paid)

Bank account: Bank Pekao S.A.
nr 90 1240 6003 1111 0000 4946 7594

The company registered in the District Court for
the Capital City of Warsaw, XIIIth Commercial Division