



EC Declaration of Conformity



according to the Directive 98/79/EC
(For self-testing)

Manufacturer: Safecare Biotech (Hangzhou) Co., Ltd.

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EC Representative: Share Info GmbH
Heerdter Lohweg 83, 40549 Düsseldorf

We, the manufacturer, declare under our sole responsibility that

the medical device(s) Product Name COVID-19 & Influenza A+B Antigen Combo Rapid Test

Type/model, identification of product allowing traceability (Where applicable) Cassette(FCO-6032H)

of Category For Self testing

is/are in conformity with the relevant provisions and requirements of Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Applied harmonised standards, national standards or other normative documents	EN ISO23640:2015	EN ISO 18113-1:2011
	EN 13612:2002	EN ISO 18113-4:2011
	EN 13641:2002	EN ISO 15223-1:2021
	EN ISO 14971:2019	EN 62366-1:2015
	ISO13485:2016	EN13532:2002

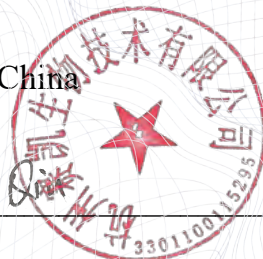
Conformity assessment procedure **EC Declaration of Conformity(Annex III,- Section 6)**

Notified Body CeCert Sp. z o.o.
(name & number) Notified Body number : 2934

Signed on: 2022-3-11 Place: Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer)

Kebin Qiu



Name of authorized signatory: Kebin, Qiu
Position held in the company: General Manager
Seal/Stamp: