CE

EC Declaration of Conformity

CE

according to the Directive 98/79/EC

(For self-testing)

Manufacturer:	Safecare Biotech （Hangzhou）Co., Ltd.
Address:	Building 2/203, No.18 Haishu Rd.Cangqian Sub-district， Yuhang District, Hangzhou, Zhejiang China 311121 Tel/Fax: +86 571 81389219 Email: admin@safecare.com.cn
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 (name & number)	CeCert Sp. z o.o. Notified Body number : 2934	

Signed on: 2021.3.17 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: