



EC Declaration of Conformity



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 13612:2002
EN 13641:2002
EN ISO 14971:2019
ISO13485:2016

EN ISO 18113-1:2011
EN ISO 18113-4:2011
EN ISO 15223-1:2021
EN 62366-1:2015
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:

2021.3.11

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:

