



# 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)

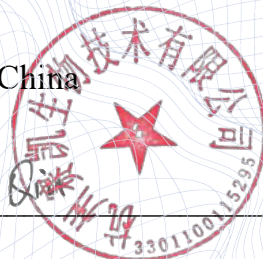
CeCert Sp. z o.o.  
Notified Body number : 2934

Signed on: 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: