



EC Declaration of Conformity



according to the Directive 98/79/EC
(For self-testing of ANNEX II of IVDD)

Manufacturer:

Safecare Biotech (Hangzhou) Co., Ltd.

Address:

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District, Hangzhou, Zhejiang China 311121
Tel/Fax: +86 571 81389219 Email: admin@safecare.com.cn

EC Representative: NIC GmbH

Erlenweg 13,49076 Osnabrück,Germany

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	COVID-19 Antigen Rapid Test Kit(Swab) For Self-testing
	Type/model, identification of product allowing traceability (Where applicable)	Cassette(Cov Ag-6012H)
of Category	: Self-test of Annex II	

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 18114-1:2011
EN ISO15223-1:2016
EN13532: 2002
EN 62366:2015
EN ISO 17511:2003

Conformity
assessment procedure

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

Notified Body
(name & number)

POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.
Notified Body number : 1434

Signed on: 2021. 6. 10 Place: Hangzhou, Zhejiang, China

Signature (on behalf of the manufacturer)



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