EC DECLARATION OF CONFORMITY

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博拓生物 BiotesT

EC Declaration of Conformity

Manufacturer:

Name：HANGZHOU BIOTEST BIOTECH CO., LTD

Address: No. 17, Futai Road, Zhongtai Street, Yuhang District, Hangzhou -311121 P.R. China

European Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: COVID-19 Antigen Rapid Test Cassette(Nasal Swab)

Catalog Number: ICOVN-C81H(Brand Name: RightSign, ExactSign)
302282(Brand Name: Sienna)

Classification: Annex II, Self-testing Device of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III section 6

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. Hangzhou Biotest takes exclusive responsibility for this declaration of conformity.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard Applied: EN ISO 13485:2016, EN ISO14971:2012, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN13532:2002, EN ISO 17511:2003, EN ISO 15193:2009, EN ISO 15223-1:2016, EN ISO 15194:2009, EN ISO 23640:2015, EC 1272/2008

Notified Body：

Name：POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.

Address：ul. Puławska 469 02-844 Warszawa Poland

Identification number: CE1434

(EC) Certificate(s): 1434-IVDD-455/2021

Expire date of the Certificate: 2024-05-27

Start of CE Marking: 2021-09-01

Place, Date of Issue: Hangzhou, P.R. China, Oct. 29, 2021

Signature: Super Liu

Name : Super Liu

Position : Quality Director

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