EC DECLARATION OF CONFORMITY ☆ EC DECLARATION OF CONFORMITY

博拓生物 BiotesT

EC Declaration of Conformity

Manufacturer:

Name：HANGZHOU BIOTEST BIOTECH CO.,LTD

Address：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: HCV Rapid Test Cassette

Catalog Number: IHCV-C31 Brand Name: RightSign/Ovios

Classification: *Annex II, List A of IVDD 98/79/EC*

Conformity Assessment Route: *IVDD 98/79/EC Annex IV*

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: 2009/886/EC, EC 1272/2008, EN ISO 13485:2016, EN 13612:2002, EN 13641:2002, EN ISO 14971:2012, EN ISO 15193:2009, EN ISO 15194:2009, EN ISO 15223-1:2016, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13975:2003, EN ISO 23640:2015

Notified Body：

Name: Polskie Centrum Badan I Certyficacji S.A.

Address: Ul. Klobucka 23A 02-699 Warszawa Poland

Identification number: CE1434

(EC) Certificate(s): 1434-IVDD-122/2021, 1434-IVDD-123/2021

Expire date of the Certificate: 2024.05.27

Start of CE Marking: 2021.04.06

Place, Date of Issue: Hangzhou, P.R. China, March 25, 2021

Signature:

Name : Wu shujiang

Position : General Manager

CE 1434