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: COVID-19 IgG/IgM Rapid Test Cassette

Catalog Number: INGM-MC42; INGM-MC42-10
Brand : Lumiratek
Classification: ***Non listed Devices of IVDD 98/79/EC***

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

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.

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:
IVDD 98/79/ EC, EN ISO13485:2016, EN ISO14971:2012, EN ISO 18113- 1:2011, EN ISO 18113-2:2011, EN 13612:2002, EN ISO 17511:2003, EN ISO 15193: 2009, EN ISO 15194:2009, EN 13641:2002, EN ISO 15223-1:2016, EN ISO 23640:2015, EN 13975:2003, EC 1272/2008

Place, Date of Issue: Hangzhou, P.R. China, March 26, 2020

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Signature:
Name : Wu shujiang
Position : General Manager