



杭州隆基生物技术有限公司  
Hangzhou Clongene Biotech Co., Ltd.

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## EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Hangzhou Clongene Biotech Co., Ltd.**  
**No.1 Yichuang Road, Yuhang Sub-district**  
**Yuhang District**  
**311121 Hangzhou**  
**China**

We declare under our sole responsibility that

the medical device: **COVID-19/Influenza A+B Antigen Combo Rapid Test**

of class: **Other**  
according to article 9 of directive 98/79/EC

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: **Directive 98/79/EC Annex III, excluding Section 6**

Applicable standards: **EN ISO 13485:2016** **EN ISO 15223-1:2021**  
**EN ISO 18113-1:2011** **EN ISO 18113-2:2011**  
**EN ISO 23640:2015** **EN ISO 14971:2019**  
**EN 13641:2002** **EN13612:2002/AC:2002**  
**EN 13975:2003** **EN 62366-1:2015**  
**EN ISO 17511:2021**

Name and address of the authorized representative: **Shanghai International Holding Corporation GmbH (Europe)**  
**Eiffestrasse 80**  
**20537 Hamburg**  
**Germany**

Hangzhou, May 12, 2022

Place, date

杭州隆基生物技术有限公司  
HANGZHOU CLONGENE BIOTECH CO., LTD.

Shujian Zheng, Legal representative

Name and function