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 Antigen Rapid Test

of class: Other
according to aticle 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
Standards Applied: EN ISO 13485:2016 EN ISO 15223-1:2016
EN ISO 23640:2015 EN 13612:2002/AC:2002
EN 13975:2003 EN ISO 14971:2012
EN ISO 18113-1:2011 EN ISO 18113-2:2011
EN 62366-1:2015

Name and address of the
Authorised Representative:

Shanghai International Holding Corporation GmbH (Europe) Eiffestrasse 80
20537 Hamburg
Germany

Hangzhou, July, 15, 2020 Shujian Zheng, Legal representative Place, date Name and function