

DECLARATION OF CONFORMITY

MANUFACTURER Qingdao Hightop Biotech Co., Ltd.
No.369 Hedong Road, Hi-tech Industrial Development Zone,
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EUROPEAN REPRESENTATIVE MedNet EC-REP GmbH
Borkstrasse 10 · 48163 Muenster · Germany

PRODUCT SARS-CoV-2 Antigen Rapid Test
--- Analyte: SARS-CoV-2 Antigen

CLASSIFICATION Self-testing

CONFORMITY ASSESSMENT ROUTE IVDD 98/79/EC Annex III section 6

WE, THE MANUFACTURER, IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY. WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATIONS ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED 98/79/EC, EN ISO 18113-1: 2011, EN ISO 18113-2:2011, EN ISO 18113-4: 2011, EN 13612: 2002, EN ISO 23640: 2015, EN 13641: 2002, EN ISO 15223-1: 2016, EN 13975: 2003, EN ISO 14971: 2019, EN ISO 13485: 2016, EN ISO 17511: 2003, EN 62366-1: 2015, EN 13532: 2002.

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SIGNATURE


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 1434