

## DECLARATION OF CONFORMITY

**MANUFACTURER** Qingdao Hightop Biotech Co., Ltd.  
No.369 Hedong Road, Hi-tech Industrial Development Zone,  
Qingdao, Shandong, 266112, China

**EUROPEAN REPRESENTATIVE** MedNet EC-REP GmbH  
Borkstrasse 10 · 48163 Muenster · Germany

**PRODUCT** SARS-CoV-2/Flu A+B/RSV Antigen Rapid Test  
--- Analyte: SARS-CoV-2 Antigen, Flu A+B Antigen,  
RSV antigen

**CLASSIFICATION** Others

**CONFORMITY ASSESSMENT ROUTE** IVDD 98/79/EC Annex III (Excluding 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 13612: 2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO 15223-1: 2016, EN 13975:2003, EN ISO 14971:2012, EN ISO 13485: 2016, EN ISO 17511: 2003, EN 62366-1:2015.

**PLACE, DATE OF ISSUE** Qingdao, 2020-12-23

**SIGNATURE**

  
  
Mr. Frank Yang  
General Manager

CE