

# 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 Antigen Rapid Test  
---Analyte: SARS-CoV-2 Antigen in human nasal swab

**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 13612: 2002, EN ISO 23640:2015, EN 13641: 2002, ISO 15223-1: 2021, EN 13975:2003, EN ISO 14971:2019, EN ISO 13485: 2016, ISO 17511: 2020, EN 62366-1:2015.

**NOTIFIED BODY** Polish Centre For Testing And Certification

**EC Certificate No.** 1434-IVDD-450/2021

**PLACE, DATE OF ISSUE** Qingdao, 2021-08-27

**SIGNATURE**

  
  
Mr. Frank Yang  
General Manager

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