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 IgM/IgG Antibody Rapid Test (Immunochromatography) Format: Panel --- Analyte：SARS-CoV-2 IgM Antibody and SARS-CoV-2 IgG Antibody SARS-CoV-2 IgM/IgG Antibody Rapid Test (Immunochromatography) Format: Cassette --- Analyte：SARS-CoV-2 IgM Antibody and SARS-CoV-2 IgG Antibody SARS-CoV-2 IgG Antibody Rapid Test (Immunochromatography) Format: Cassette --- Analyte：SARS-CoV-2 IgG Antibody SARS-CoV-2 IgM Antibody Rapid Test (Immunochromatography) Format: Cassette --- Analyte：SARS-CoV-2 IgM Antibody
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 DOCUMENTATION IS 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，2020-4-30

SIGNATURE

Mr. Frank Yang

General Manager

CE