

Declaration of Conformity

Manufacturer.....: Shenzhen CAS-Envision Medical Technology Co., Ltd.

Address.....: 4F, Bldg 4, Tusincere Technology Park, No. 333
Longfei Avenue, Longcheng, Longgang, Shenzhen,
Guangdong, China

European Representative...: Riomavix S.L.
Calle de Almansa 55,1D, Madrid 28039 Spain

Product.: SARS-CoV-2 Antigen Rapid Detection Kit(25 Tests)
SARS-CoV-2 Antigen Rapid Detection Kit(5 Tests)
SARS-CoV-2 Antigen Rapid Detection Kit(1Test)

Product Classification.: Others
Conformity Assessment.....: IVDD
Route...: European Council Directive 98/79/EC

We, the Manufacturer, herewith declare with sole responsibility that our products mentioned above meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

General applicable directives:

In Vitro Diagnostic Medical Devices Directive: IVDD 98/79/EC Applicable standards:

EN ISO 14971:2012	EN ISO 18113-1:2011
EN ISO 18113-2:2011	EN ISO 13612:2002/AC:2002
EN ISO 23640:2015	EN ISO 15233-1:2016
EN ISO 17511:2003	EN 13975:2003



Tianzhu Wu
General Manager
Date: Dec. 03, 2020