EC DECLARATION OF CONFORMITY

CE

Manufacturer Address	Manufacture Name: Hunan Runmei Gene Technology Co., Ltd. Post Add: Room 401-1, Building 3, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District, Changsha, Hunan Province, China. 410153.
European Representative	Authorized Representative Name: Riomavix S.L. Add: Calle de Almansa 55, 1D, Madrid 28039 Spain
Product Information	Product Name:SARS-CoV-2 （COVID-19） Saliva Antigen Rapid Test Kit(Lollipop Design) Cat. No.:RM-E-G1240 Specification:1test/kit;20 tests/kit; 30 tests/kit; 50 tests/kit
Classification **Basic UDI-DI**	Others 697411595SJ2U
Conformity Assessment Route: Annex VIII	*We, Hunan Runmei Gene Technology Co., Ltd, under our sole responsibility declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.*
General Applicable Directives	*In vitro diagnostic medical devices directive:* *DIRECTIVE 98/79/EC OF THE EUROPEAN PARLLAMENT AND OF THE COUNCIL OF 27 October 1998 on in vitro diagnostic medical devices.*
Standards Applied	EN 13612:2016 EN ISO 14971: 2019 EN ISO 18113-1: 2011 EN ISO 15223-1: 2016 EN ISO 13485:2016 EN ISO 23640:2015 EN ISO 18113-2: 2011 EN 13641: 2002

Place: Changsha City, Hunan Province, China.
Date: December 20, 2021

Name: Jian Gong
Position: Managing Director
Signature: JianGong