Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device
We,

Nanjing Vazyme Medical Technology Co., Ltd
Floor 1-3, Buliding C2, Red Maple Park of Technological Industry,
Kechuang Road, Economy & Technology Development Zone,
Nanjing, China.

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

EN 13975:2003; EN ISO 18113-2:2011; EN ISO 13485:2016; EN ISO 14971.2019; EN 13612:2002/AC:2002; EN ISO 17511:2003; EN ISO 15193:2009; EN ISO 15194:2009; EN ISO 23640:2015; EN 13641:2002; EN ISO 15223-1:2016; EN 1041:2008

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Date : 26/10/2020
Stamp

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