



## 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, Building C2, Red Maple Park of Technological Industry, Kechuang Road, Economy & Technology Development Zone, Nanjing, China.**

Declare under our sole responsibility that the following self-testing 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)**

***Catalogue: C8611CH / C8610CH / C8602CH***

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 OR Annex IV except point 4 & 6:

- 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. By

**POLISH CENTRE FOR TESTING AND CERTIFICATION Notified Body No. 1434, 469 Pulawska Street, 02-844 Warsaw, Company registered in the XIII Economic Division of the District Court of the Capital City of Warsaw under KRS No. 0000144813**

CE Certificate's details:

No.: 1434-IVDD-463/ 2021

Date of Issue: 30. 09. 2021





Our current Quality System is formatted to international standards:

EN ISO 18113-2:2011, EN ISO 18113-4:2011, EN ISO 13485:2016, EN ISO 14971:2012, 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

#### Corporate Contact Information

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Position: CEO

SIGNATURE :

Date: 01. 10. 2021

Stamp

 *Tang Bo*

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