

# EC Declaration of Conformity

Manufacturer: Amazing Biotech (Shanghai) Co., LTD  
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European Representative: Riomavix Sociedad Limitada  
Calle de Almansa 55, 1D, Madrid 28039 Spain  
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Product Name: COVID-19/Influenza A/B & ADV/RSV Antigen Tube Test

Classification: **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, 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 98/79/EC

Harmonized standards:

EN ISO 13485:2016  
EN ISO 15223-1:2016  
EN ISO 14971:2012  
EN ISO 18113-2:2011  
EN 13612:2002  
EN ISO 17511:2003  
EN ISO 23640:2015

Signature:

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(Zhongren Zhou)

Title: General Manager

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