AZUBIO DIAGNOSTICS CO., LTD
No. 219, Guangzhushan Road, Dipu Street, Anji County, Huzhou, 313399 Zhejiang, China
Tel: 0572-5832377 E-mail: contact@azubio.com

# EU DECLARATION OF CONFORMITY (No.: DOC-D006)

## According Regulation (EU) 2017/746 on in vitro diagnostic medical devices

| | |
|---|---|
| **Manufacturer:** | Azubio Diagnostics Co., Ltd.<br>No. 219, Guangzhushan Road, Dipu Street, Anji County, Huzhou, 313399 Zhejiang, China |
| **SRN:** | CN-MF-000032581 |
| **European Representative:** | CMC Medical Devices & Drugs S.L<br>C/Horacio Lengo Nº 18, CP 29006, Málaga-Spain |
| **AR's SRN:** | ES-AR-000000293 |
| **Product Name:** | FLU A&B/ RSV&ADV/HMPV/COV Combo Pen Home Test |
| **Basic UDI-DI:** | 697945273A4D660HFZ |
| **Intended Purpose:** | The FLU A&B/ RSV&ADV/HMPV/COV Combo Pen Home Test is an in vitro immunoassay. The assay is for the direct and qualitative detection of viral antigens of SARS-CoV-2 (COVID-19), influenza A virus (FLUA), influenza B virus (FLUB), adenovirus (ADV), respiratory syncytial virus (RSV), and human metapneumovirus (HMPV) in nasal swab specimens from individuals with signs and symptoms of respiratory tract infection, or from those who are suspected of infected with SARS-CoV-2, influenza A virus, influenza B virus, adenovirus, respiratory syncytial virus and/or human metapneumovirus.<br>The test is for diagnosing the six (6) kinds of respiratory viruses infection mentioned above. The test is authorized for home use with self-collected nasal swab specimens directly from individuals. Children aged between 2 and 18 years old must be supervised or aided by an adult when carrying out the test. The test procedure is not automated. The test does not replace laboratory testing or clinical evaluation for establishing a diagnosis; consultation with a physician for medical assessment is required. |
| **Reference Number:** | A4D660H11, A4D660H12, A4D660H14, A4D660H15, A4D660H21, A4D660H22, A4D660H24, A4D660H25, A4D660H31, A4D660H32, A4D660H34, A4D660H35 |
| **Classification acc. to IVDR Annex VIII:** | Class C, Rule 4a of IVDR Annex VIII |
| **Conformity Assessment Procedure:** | Annex IX of Regulation (EU) 2017/746 |
| **CE Certificate No.:** | 6188356CE02 |
| **TD certificate: No.:** | 6188356TD02 |
| **Name and ID of the Notified Body:** | DEKRA Certification B.V.<br>NB Number: 0344 |

We, the Manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746 on *In Vitro* Diagnostic Medical Devices (IVDR). All supporting documentations are retained under the premises of the manufacturer.

Huzhou, 2026.08.07

**Place, date**

**Legally binding signature, General Manager**