**Number: 6188356TD02**

# EU Technical Documentation Assessment Certificate

**Conformity Assessment Regulation 2017/746 on In Vitro Diagnostic devices, Annex IX Chapter II and III**

Manufacturer:

## Azubio Diagnostics Co., Ltd.

**No. 219, Guangzhushan Road, Dipu Street, Anji County,**
**Huzhou, 313399 Zhejiang**
**China**
**SRN ID.: CN-MF-000032581**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

# 0344

**Supplement to certificate: 6144578CN**

**Additional certificate: 6188356CE02**
**Authorized Representative:**
**CMC Medical Devices & Drugs S.L**
C/Horacio Lengo Nº 18, CP 29006, Málaga-Spain

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/746, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/746. For placing these products on the market an Annex IX EU Quality Management System certificate is also required.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

F. Godeke
Principal Certification Manager

First Issued: **06 August 2026** Date: **06 August 2026** Expiry date**: 01 August 2031**

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This certificate covers the following device(s):

| **Class C, Self-testing** | |
|---|---|
| **Basic UDI-DI:** 697945273A4D660HFZ<br><br>**Device Name:** FLU A&B/ RSV&ADV/HMPV/COV Combo Pen Home Test<br><br>**Type:** W0105 INFECTIOUS DESEASES<br>**Model:**<br>A4D660H11, A4D660H12, A4D660H14, A4D660H15, A4D660H21, A4D660H22, A4D660H24, A4D660H25, A4D660H31, A4D660H32, A4D660H34, A4D660H35 | *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 infect-ed 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.* |
| **Basic UDI-DI:** 697945273A49560HCC<br><br>**Device Name:** FLU A&B/ RSV&ADV/ COV Combo Pen Home Test<br><br>**Type:** W0105 INFECTIOUS DESEASES<br>**Model:**<br>A49560H11, A49560H12, A49560H14, A49560H15, A49560H21, A49560H22, A49560H24, A49560H25, A49560H31, A49560H32, A49560H34, A49560H35 | *Intended Purpose: The FLU A&B/ RSV&ADV/COV Combo Pen Home Test is an in vitro immuno-assay. 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), and respiratory syncytial virus (RSV) 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, and/or respiratory syncytial virus.*<br>*The test is for diagnosing the five (5) 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* |

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| | *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.* |
| **Basic UDI-DI:** 697945273A47660HBV<br><br>**Device Name:** FLU A&B/ COVID-19 Combo Pen Home Test<br><br>**Type:** W0105 INFECTIOUS DESEASES<br>**Model:**<br>A47660H11, A47660H12, A47660H14, A47660H15, A47660H21, A47660H22, A47660H24, A47660H25, A47660H31, A47660H32, A47660H34, A47660H35 | *Intended Purpose: The FLU A&B/ COVID-19 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) and influenza B virus (FLUB) 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, and/or influenza B virus.*<br>*The test is for diagnosing the three (3) 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.* |
| **Basic UDI-DI:** 697945273A48410HAZ<br><br>**Device Name:** COVID-19 Antigen Pen Home Test<br><br>**Type:** W0105 INFECTIOUS DESEASES<br>**Model:**<br>A48410H11, A48410H12, A48410H14, A48410H15, A48410H21, A48410H22, A48410H24, A48410H25, A48410H31, A48410H32, A48410H34, A48410H35 | *Intended Purpose: The COVID-19 Antigen Pen Home Test is an in vitro immunoassay. The assay is for the direct and qualitative detection of viral antigens of SARS-CoV-2 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.*<br>*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.* |

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| **Basic UDI-DI:** 697945273A46060HA8<br><br>**Device Name:** Influenza A/B Antigen Pen Home Test<br><br>**Type:** W0105 INFECTIOUS DESEASES<br>**Model:**<br>A46060H11, A46060H12, A46060H14, A46060H15, A46060H21, A46060H22, A46060H24, A46060H25, A46060H31, A46060H32, A46060H34, A46060H35 | *Intended Purpose: The Influenza A/B Antigen Pen Home Test is an in vitro immunoassay. The assay is for the direct and qualitative detection of viral antigens of influenza A virus and influenza B virus in nasal swab specimens from individuals with signs and symptoms of respiratory tract infection, or from those who are suspected of infected with influenza A virus and/or influenza B virus .*<br>*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.* |

**Certificate History**

*Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.*

| Revision | Date of Issue certificate | Certification Notice Reference | Action |
|---|---|---|---|
| 0 | 06 August 2026 | 6144578CN07 | First issue |

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