明德生物

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Wuhan EasyDiagnosis Biomedicine Co., Ltd.**
Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator, No.388, Gaoxin 2nd RD, East Lake Hi-Tech Development Zone,430074 Wuhan, China

Authorized EU Representative: **Osmunda Medical Technology Service GmbH**
Treskowallee 108, 10318 Berlin, Germany

DIMDI No.: **DE/0000047267**

We,as manufacturer,declare under our sole responsibility that:

Product Name: **COVID-19 (SARS-CoV-2) Antigen Test Kit**
Analyte: Nucleocapsid protein antigen from SARS-CoV-2 in nasal swab from individual suspected of COVID-19

Type/Model:

Specification	REF
1 Test/kit	W-AgH-01, W-AgH-01S
5 Tests/Kit	W-AgH-05, W-AgH-05S
7 Tests/Kit	W-AgH-07, W-AgH-07S
8 Tests/Kit	W-AgH-08, W-AgH-08S
10 Tests/Kit	W-AgH-10, W-AgH-10S
15 Tests/Kit	W-AgH-15, W-AgH-15S
20 Tests/Kit	W-AgH-20, W-AgH-20S
25 Tests/Kit	W-AgH-25, W-AgH-25S

of class: **self-test**
according to direct. 98/79/EC

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it.

Conformity assessment procedure: **Directive 98/79/EC Annex III （section 6）**

list of applied standard: ISO 14971:2019, EN ISO 15223-1: 2016, EN ISO 13485:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN13612:2002, EN 13612:2002/AC:2002, EN ISO 23640:2015 EN 62366-1-2015, EN 13532-2002, EN 18113-4-2013

Notified Body: **Polish Centre for Testing and Certification**
469 Puławska Street, 02-844 Warsaw, Poland

Identification number:1434

(EC)Certificate(s): **No.1434-IVDD-444/2021**

Start of CE-Marking: **July 13,2021**

Wuhan, July 28 ,2021
Place, date

Name and function: Yingwen Zhao,regulatory representative

Wuhan EasyDiagnosis Biomedicine Co., Ltd 武汉明德生物科技股份有限公司

CE 1434