

**EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ**

Name und Adresse des Herstellers: / **Wuhan EasyDiagnosis Biomedicine Co., Ltd.**
Name and address of the manufacturer: / Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1 Wuhan Optics Valley
Nom et adresse du fabricant: / International Biopharmaceutical Enterprise Accelerator, No.388,
Nome e indirizzo del fabbricante: Gaoxin 2nd RD, East Lake Hi-Tech Development Zone,430074
Wuhan, China

EU-Vertreter/
Authorized EU Representative/
représentants européens / **MedNet EC-REP GmbH**
Presentanti dell'UE: **Borkstrasse 10, 48163 Münster, Germany**
DIMDI No.: **DE/0000048589**

Wir erklären in alleiniger Verantwortung, dass / We ,as manufacturer,declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / **COVID-19 (SARS-CoV-2) Antigen Test Kit**
the medical device: /
Product Name: / **Analyte: See attachment.**

Type/Model:
le dispositif médical: / **See attachment.**
il dispositivo medico:

der Klasse: / **Other Device**
of class: /
de la classe: /
di classe:

Nach Richtlinie 98/79/EG / selon directive 98/79/CE
secondo direttiva 98/79/CE / according to direct. 98/79/EC

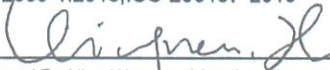
den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht.
meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it.
remplit toutes les exigences de la directive sur les selon directive 98/79/CE et de ses transpositions en droit national qui le concernent.
soddisfa tutte le disposizioni della direttiva 98/79/CE e della loro trasposizione nel diritto nazionale che lo riguardano.

Conformity assessment procedure: / **Directive 98/79/EC Annex III(Excluding 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,ISO 20916: 2019

Wuhan, December 10, 2021

Ort, Datum / Place, date /
Lieu, date / Luogo, data


Name und Funktion / Name and function: Yingwen.Zhao/regulatory representative
Nom et fonction / Nome e funzione





CE

Type/model	REF		Type/model	REF	
A	W-Ag01-01	W-Ag05-20	B	W-Ag04-B01	W-Ag05-B20
	W-Ag01-05	W-Ag06-01		W-Ag04-B05	W-Ag06-B01
	W-Ag01-10	W-Ag06-05		W-Ag04-B10	W-Ag06-B05
	W-Ag01-20	W-Ag06-10		W-Ag04-B20	W-Ag06-B10
	W-Ag02-01	W-Ag06-20		W-Ag02-B01	W-Ag06-B20
	W-Ag02-05	W-Ag07-01		W-Ag02-B05	W-Ag07-B01
	W-Ag02-10	W-Ag07-05		W-Ag02-B10	W-Ag07-B05
	W-Ag02-20	W-Ag07-10		W-Ag02-B20	W-Ag07-B10
	W-Ag03-01	W-Ag07-20		W-Ag03-B01	W-Ag07-B20
	W-Ag03-05	W-Ag08-01		W-Ag03-B05	W-Ag08-B01
	W-Ag03-10	W-Ag08-05		W-Ag03-B10	W-Ag08-B05
	W-Ag03-20	W-Ag08-10		W-Ag03-B20	W-Ag08-B10
	W-Ag04-01	W-Ag08-20		W-Ag04-B01	W-Ag08-B20
	W-Ag04-05	W-Ag09-01		W-Ag04-B05	W-Ag09-B01
	W-Ag04-10	W-Ag09-05		W-Ag04-B10	W-Ag09-B05
	W-Ag04-20	W-Ag09-10		W-Ag04-B20	W-Ag09-B10
	W-Ag05-01	W-Ag09-20		W-Ag05-B01	W-Ag09-B20
	W-Ag05-05			W-Ag05-B05	
W-Ag05-10		W-Ag05-B10			