



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

Name und Adresse des Herstellers: /  
Name and address of the manufacturer: /  
Nom et adresse du fabricant: /  
Nome e indirizzo del fabbricante:

**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

EU-Vertreter/  
Authorized EU Representative/  
représentants européens /  
Presentanti dell'UE:  
DIMDI No.:

**MedNet EC-REP GmbH Borkstrasse 10, 48163 Münster,  
Germany**  
  
**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: /  
the medical device: /  
Product Name: /

**COVID-19 (SARS-CoV-2) Antigen Test Kit**  
**GMDN Code:64787**  
**Analyte:** nucleocapsid protein antigen from SARS-CoV-2 in  
oropharyngeal (throat) swabs, nasopharyngeal swabs and nasal  
swabs from individuals suspected of COVID-19 by their healthcare  
provider.

Type/Model:  
le dispositif médical: /  
il dispositivo medico:

**REF: See attachment.**

der Klasse /  
of class: /  
de la classe: /  
di classe:

**Others**

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**

list of applied standard:

EN ISO 14971:2019, EN ISO 13485:2016,  
EN ISO 13485:2016, EN ISO 18113:2011,  
EN ISO 18113-2:2011, EN13612:2002,  
EN 13612:2002/A3:2002, EN ISO 23040:2015  
EN 62366-1:2015

Wuhan, July 9,2021

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

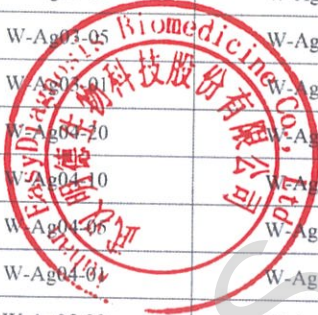
Name und Funktion / Name and function, Yangwen Zhao/regulatory representative  
Nom et fonction / Nome e funzione





CE

REF	
W-Ag02-20	W-Ag02-B20
W-Ag02-10	W-Ag02-B10
W-Ag02-05	W-Ag02-B05
W-Ag02-01	W-Ag02-B01
W-Ag03-20	W-Ag03-B20
W-Ag03-10	W-Ag03-B10
W-Ag03-05	W-Ag03-B05
W-Ag03-01	W-Ag03-B01
W-Ag04-20	W-Ag04-B20
W-Ag04-10	W-Ag04-B10
W-Ag04-06	W-Ag04-B05
W-Ag04-01	W-Ag04-B01
W-Ag05-20	W-Ag05-B20
W-Ag05-10	W-Ag05-B10
W-Ag05-05	W-Ag05-B05
W-Ag05-01	W-Ag05-B01
W-Ag06-20	W-Ag06-B20
W-Ag06-10	W-Ag06-B10
W-Ag06-05	W-Ag06-B05
W-Ag06-01	W-Ag06-B01



For business use only

