



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

**COVID-19 Antigen Rapid Test Kit (Saliva/Swabs)**  
Analyte:antigen from SARS-CoV-2 in saliva and oropharyngeal  
(throat)/nasopharyngeal swabs

**Saliva:**  
20 Tests/Kit, 10 Tests/Kit, 5 Tests/Kit, 2 Tests/Kit, 1 Test/Kit  
**Oropharyngeal/Nasopharyngeal swabs:**  
40 Tests/Kit, 20 Tests/Kit, 5 Tests/Kit, 2 Tests/Kit, 1 Test/Kit

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 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

Wuhan, January 22, 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