



明德生物



**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 (SARS-CoV-2) IgM/IgG Antibody Test Kit
Analyte: IgM and IgG Antibody for SARS-CoV-2
20 tests/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.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Richtlinie 98/79/EG Anhang III
Directive 98/79/EC Annex III
Directive 98/79/CE Annexe III
Direttiva 98/79/CE senza Allegato III

Wuhan, March 08,2020

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

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

