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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:	**MedNet EC-REP GmbH 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: / the medical device: / Product Name:/ Type/Model: le dispositif médical: / il dispositivo medico:	**Procalcitonin (PCT)Test Kit（Immunofluorescence Method）** Analyte:PCT **20 tests/kit ; 40 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 Allegato III**

Digitally signed by Marinescu Traian alin
Date: 2024.01.09 12:57:38 EET
Reason: MoldSign Signature
Location: Moldova

Wuhan, July. 13, 2020
Ort, Datum / Place, date / Lieu, date / Luogo, data

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

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das Medizinprodukt: / the medical device: / Product Name:/ Type/Model: le dispositif médical: / il dispositivo medico:	**N-terminal pro-brain Natriuretic Peptide(NT-proBNP) Test Kit (Immunofluorescence Method)** **Analyte: NT-proBNP** **20 tests/kit ; 40 tests/kit**
der Klasse: / of class: / de la classe: / di classe:	**Others**

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Konformitätsbewertungsverfahren: /	**Richtlinie 98/79/EG Anhang III**
Conformity assessment procedure: /	**Directive 98/79/EC Annex III**
Procédure d'évaluation de la conformité: /	**Directive 98/79/CE Annexe III**
Procedura di valutazione della conformità:	**Direttiva 98/79/CE Allegato III**

Wuhan, September, 2, 2020
Ort, Datum / Place, date /
Lieu, date / Luogo, data

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

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das Medizinprodukt: / the medical device: / Product Name:/ Type/Model: le dispositif médical: / il dispositivo medico:	**High-Sensitivity Cardiac Troponin I (hs-cTnI) Test Kit (Immunofluorescence Method)** **Analyte: hs-cTnI** **20 tests/kit ; 40 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

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

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EC DECLARATION OF CONFORMITY

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

SRN: CN-MF-000019908

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany

SRN: DE-AR-000000002

Self-Declaration Statement

We, **Wuhan EasyDiagnosis Biomedicine Co., Ltd.** under our sole responsibility declare that the mentioned product, Fluorescence Immunity Analyzer meet the provisions of the EC Council Directives and Standards (Please see below Standards Applied information). All supporting documentations are retained under the premises of the manufacturer.

Basic UDI-DI : 697372013IFQFT001ZH

General Applicable Directives Regulation (EU) 2017/746

Standards Applied

EN ISO 14971:2019	EN 61326-1:2013
EN ISO 13485:2016	EN 61326-2-6:2013
EN ISO 15223-1:2021	EN 61010-1:2010/A1:2019/AC:2019
EN ISO 18113-1:2011	EN IEC 61010-2-081:2015
EN ISO 18113-2:2011	EN 61010-2-101:2017
EN 13612:2002/AC:2002	IEC 62304:2015+AMD1:2015
	EN 62366-1:2015

Product Information
Name: Fluorescence Immunity Analyzer
Model: QFT9000
Classification: Class A
Classification rule: ANNEX VIII, rule 5(b)
Conformity Assessment Route: Annex II & ANNEX III

Intended Use
The Fluorescence Immunity Analyzer adopts the fluorescence immunoassay method. It is used with the kit produced by our company to conduct quantitative and qualitative testing of analyte in whole blood, serum and plasma samples from human body. By providing the measurement results of these parameters and combining with calculated parameter values, it helps medical staff quickly get patient information, so as to improve the diagnose and treatment quality of doctors for patients. The instrument supports a variety of display and printing and can be simply operated, with rich and practical functions. Trained laboratory doctors, clinicians and nurses can test the blood samples and manage testing data with this analyzer.

Caution: For professional use only.

Signature & Stamp
Name: Mr. Zhao. Yingwen
Title: management representative
Signature:
Date: 2022.6.28