



**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 Borkstrasse 10, 48163 Münster,**  
Presentanti dell'UE: **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: / **High-Sensitivity Cardiac Troponin I (hs-cTnI) Test Kit**  
the medical device: / **(Immunofluorescence Method)**  
Product Name: / **Analyte: hs-cTnI**  
Type/Model: **20 tests/kit ; 40 tests/kit**  
le dispositif médical: /  
il dispositivo medico:

der Klasse: / **Others**  
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.

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







明德生物



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the medical device: /  
Product Name: /  
Type/Model:  
le dispositif médical: /  
il dispositivo medico:

**Whole-process C-reactive protein (hs-CRP+conventional CRP)  
Test Kit (Immunofluorescence Method)  
Analyte: hs-CRP+conventional CRP  
20 tests/kit ; 40 tests/kit**

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

**Others**

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secondo direttiva 98/79/CE / according to direct. 98/79/EC

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

Wuhan, September. 2, 2020

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


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

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Procedura di valutazione della conformità: **Direttiva 98/79/CE Allegato III**

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: / **Creatine kinase isoenzymes (CK-MB) Test Kit**  
the medical device: / **(Immunofluorescence Method)**  
Product Name:/ **Analyte: CK-MB**  
Type/Model: **20 tests/kit ; 40 tests/kit**  
le dispositif médical: /  
il dispositivo medico:

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

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Wuhan, September, 2, 2020

Ort, Datum / Place, date /  
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CMC Medical Devices & Drugs S.L.  
C/ Horacio Lengo No.18, CP 29006, Málaga, Spain

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das Medizinprodukt: /  
the medical device: /  
Product Name: /

Thyroid Stimulating Hormone(TSH) Test Kit  
(Immunofluorescence Method)

Analyte: This test kit is intended for *in vitro* quantitative detection of  
thyroid stimulating hormone (TSH) content in human  
serum/plasma/whole blood.

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

Specifacation	REF
20 tests/kit	W-IF-TSH-20
40 tests/kit	W-IF-TSH-40

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

Other Device

Nach Richtlinie 98/79/EG / selon directive 98/79/CE  
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Conformity assessment procedure: /

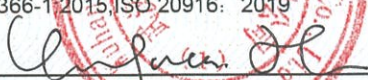
Directive 98/79/EC Annex III(Excluding section 6)

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, March 14, 2022

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

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





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Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / **Total Triiodothyronine(T3) Test Kit (Immunofluorescence Method)**  
the medical device: /  
Product Name: / **Analyte:** This test kit is intended for in vitro quantitative detection of  
triiodothyronine (T3) content in human serum/plasma/whole blood.

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

Specifacation	REF
20 tests/kit	W-IF-T3-20
40 tests/kit	W-IF-T3-40

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

**Other Device**

Nach Richtlinie 98/79/EG / selon directive 98/79/CE  
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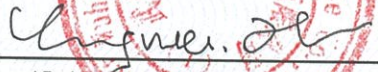
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Conformity assessment procedure: / **Directive 98/79/EC Annex III(Excluding section 6)**

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, March 14, 2022

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

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





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das Medizinprodukt: / **Free Triiodothyronine (FT3) Test Kit (Immunofluorescence Method)**  
 the medical device: /  
 Product Name: /

**Analyte:** This kit is intended for in vitro quantitative detection of free triiodothyronine (FT3) content in human serum/plasma/whole blood

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

Specification	REF
20 tests/kit	W-IF-FT3-20
40 tests/kit	W-IF-FT3-40

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

Other Device

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Conformity assessment procedure: /


**Directive 98/79/EC Annex III (Excluding section 6)**

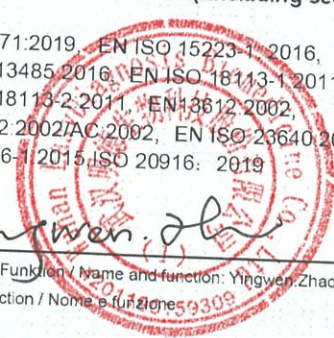
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Wuhan, March 14, 2022

Ort, Datum / Place, date /  
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 Name und Funktion / Name and function: Yingwen Zhao/regulatory representative  
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das Medizinprodukt: / **Total Thyroxine(T4) Test Kit (Immunofluorescence Method)**  
the medical device: /  
Product Name: /

**Analyte:** This kit is intended for in vitro quantitative detection of thyroxine (T4) content in human serum/plasma/whole blood

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

Specifacation	REF
20 tests/kit	W-IF-T4-20
40 tests/kit	W-IF-T4-40

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

**Other Device**

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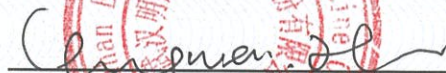
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EN 62366-1:2015, ISO 20916: 2019

Wuhan, March 14, 2022

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Lieu, date / Luogo, data

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

