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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:	**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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meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it.
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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**

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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Date: 2024.02.15 16:06:21 EET
Reason: MoldSign Signature
Location: Moldova

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

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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**

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

Mr Yingwen Zhao
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Nom et fonction / Nome e funzione

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

Nach Richtlinie 98/79/EG / selon directive 98/79//CE
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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**

Wuhan, September, 2, 2020
Ort, Datum / Place, date /
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C/ Horacio Lengo No.18, CP 29006, Málaga, Spain

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

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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 /
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Name und Funktion / Name and function: Yingwen Zhao/regulatory representative
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the medical device: /
Product Name:/

Total Triiodothyronine(T3) Test Kit (Immunofluorescence Method)

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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Wuhan, March 14, 2022
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the medical device: /
Product Name:/

Free Triiodothyronine(fT3) Test Kit (Immunofluorescence Method)

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:

Specifacation	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

Nach Richtlinie 98/79/EG / selon directive 98/79//CE
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the medical device: /
Product Name:/

Total Thyroxine(T4) Test Kit (Immunofluorescence Method)

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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