

CERTIFICATE OF REGISTRATION

MedNet GmbH
Borkstraße 10
48163 Münster
Germany

in its function of the European Authorized Representative, in accordance with the In Vitro Diagnostic Directive 98/79/EC, hereby confirms the registration of the following *in vitro* diagnostic medical device into the German DIMDI data base

**COVID19 Antigen Rapid Test Kits (Colloidal Gold)
COVID19 Antigen Quantitative Test Kits
(Immunofluorescence Assay)**
(for a detailed list please see attachment)
DIMDI Registration Number DE/CA22/419-1889-IVD

COVID19 Neutralization Antibody Products
(for a detailed list please see attachment)
DIMDI Registration Number DE/CA22/419-1890-IVD

Hormone
(for a detailed list please see attachment)
DIMDI Registration Number DE/CA22/419-1911-IVD

Cardiac Marker
(for a detailed list please see attachment)
DIMDI Registration Number DE/CA22/419-1908-IVD

HbA1c Analyzer (Boric-acid Affinity Chromatography)
(for a detailed list please see attachment)
DIMDI Registration Number DE/CA22/419-1907-IVD

Inflammation Marker
(for a detailed list please see attachment)



DIMDI Registration Number DE/CA22/419-1910-IVD

Fluorescence Immunoassay Analyzer (Immunofluorescence Chromatography),
(for a detailed list please see attachment)

DIMDI Registration Number DE/CA22/419-1891-IVD

Cancer Marker

(for a detailed list please see attachment)

DIMDI Registration Number DE/CA22/419-1909-IVD

on behalf of

Aehealth Ltd.
Unit G25 Waterfront Studios, 1 Dock Road
E161AH London
United Kingdom

according to the directive 98/79/EC of the European Parliament and of the Council of the European Union relating to *in vitro* diagnostic medical devices.

Münster, 30.09.2021

 
MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany
Phone: +49 251 322 66-61
ecrep@medneteurcpe.com www.mednet-eurep.com

Dr. Isabel Uhlenbrock

MedNet GmbH

Product list

DE/CA22/419-1889-IVD

| Products | Model | Method | Product Class |
|---|---|--------------------------|---|
| COVID19 Antigen Rapid Test Kits(Colloidal Gold) | 1test/kit, 3tests/kit, 5tests/kit, 10tests/kit, 20tests/kit, 25tests/kit, 30tests/kit, 50tests/kit, 100tests/kit | Colloidal Gold | Other device not listed under Annex II and self-testing |
| COVID19 Antigen Quantitative Test Kits (Immunofluorescence Assay) | 1test/kit, 3tests/kit, 5tests/kit, 10tests/kit, 20tests/kit, 25tests/kit, 30tests/kit, 50tests/kit, 100tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |

DE/CA22/419-1890-IVD

| Products | Model | Method | Product Class |
|--|---|-----------------------------------|---|
| COVID19 Neutralization Antibody Quantitative Test Kit (Fluorescence Immunochromatographic Assay) | 1test/kit, 3tests/kit, 5tests/kit, 10tests/kit, 20tests/kit, 25tests/kit, 30tests/kit, 50tests/kit, 100tests/kit | Immunofluorescence Chromatography | Other device not listed under Annex II and self-testing |
| COVID19 Neutralization Antibody Rapid Test Kit (Colloidal Gold) | 1test/kit, 3tests/kit, 5tests/kit, 10tests/kit, 20tests/kit, 25tests/kit, 30tests/kit, 50tests/kit, 100tests/kit | Colloidal Gold | Other device not listed under Annex II and self-testing |

DE/CA22/419-1911-IVD

| Products | Model | Method | Product Class |
|-----------------|--------------|---------------|----------------------|
|-----------------|--------------|---------------|----------------------|

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| LH (Luteinizing Hormone) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| PRL (Prolactin) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| TSH (Thyroid Stimulating Hormone) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| T4 (Total Thyroxine) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| T3 (Total Triiodothyronine) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| AMH (Anti-Mullerian Hormone) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| FSH (Follicle-stimulating Hormone) Rapid Quantitative | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |

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| Test (Immunofluorescence Assay) | tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | | |
| β-HCG (β-Human Chorionic Gonadotropin) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| PROG (Progesterone) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| TES (Testosterone) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |

DE/CA22/419-1908-IVD

| Products | Model | Method | Product Class |
|--|---|--------------------------|---|
| D-Dimer Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| HbA1c (Glycated Hemoglobin) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |

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|---|--|--------------------------|---|
| CK-MB (Creatine Kinase-MB) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| MYO (Myoglobin) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| cTnI/CK-MB/MYO (Cardiac Troponin I/Creatine Kinase-MB/Myoglobin) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| NT-proBNP (N-terminal prohormone of brain natriuretic peptide) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| cTnI (Cardiac troponin I) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| cTnT (Cardiac troponin T) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| H-FABP (Heart-type Fatty Acid Binding Protein) Rapid Quantitative Test | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit | Immunofluorescence Assay | Other device not listed under |

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|---|--|------------------------------------|---|
| (Immunofluorescence Assay) | tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | | Annex II and self-testing |
| HbA1c (Glycated Hemoglobin) Test Kit (Boric-acid Affinity Chromatography) | 5 tests/kit, 10 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit 100 tests/kit | Boric-acid Affinity Chromatography | Other device not listed under Annex II and self-testing |

DE/CA22/419-1907-IVD

| Products | Model | Method | Product Class |
|---|--|------------------------------------|---|
| HbA1c Analyzer (Boric-acid Affinity Chromatography) | LAFFINITE I, LAFFINITE II, LAFFINITE III, LAFFINITE mini, LAFFINITE Plus | Boric-acid Affinity Chromatography | Other device not listed under Annex II and self-testing |

DE/CA22/419-1910-IVD

| Products | Model | Method | Product Class |
|--|---|--------------------------|---|
| SAA (Serum amyloid A) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| PCT (Procalcitonin) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |

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| HS-CRP/CRP (High Sensitivity C-reactive protein /C-reactive protein) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| IgE (Immunoglobulin E) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| NGAL (Neutrophil Gelatinase-Associated Lipocalin) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| IL-6 (Inter-Leukin-6) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |

DE/CA22/419-1891-IVD

| Products | Model | Method | Product Class |
|---|--|-----------------------------------|---|
| Fluorescence Immunoassay Analyzer (Immunofluorescence Chromatography) | LAMUNO X, LAMUNO RX, LAMUNO Plus, LAMUNO Pro, LAMUNO Mini, LAMUNO Max, LAMUNO I, LAMUNO II, LAMUNO III, LAMUNO Vet, DrugTec I, DrugTec II, DrugTec III | Immunofluorescence Chromatography | Other device not listed under Annex II and self-testing |

DE/CA22/419-1909-IVD

| Products | Model | Method | Product Class |
|---|--|--------------------------|---|
| 25-(OH)-VD (25-OH Vitamin D) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| CEA (Carcinoembryonic Antigen) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| FER (Ferritin) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| β2-MG (Beta-2-Microglobulin) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| PGI/PGII (Pepsinogen I/ Pepsinogen II) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |
| MAU (Microalbumin) Rapid Quantitative Test (Immunofluorescence Assay) | 1 test/kit, 5 tests/kit, 10 tests/kit, 20 tests/kit, 25 tests/kit, 30 tests/kit, 50 tests/kit, 100 tests/kit | Immunofluorescence Assay | Other device not listed under Annex II and self-testing |

