



Bezirksregierung Münster

Freiverkaufszertifikat

nach Artikel 55 auch i.V.m. Artikel 110 Abs. 3 und Abs. 4 der Verordnung (EU) 2017/746 und § 10 des Medizinprodukte-Durchführungsgesetzes in der jeweils geltenden Fassung

zur Vorlage bei den zuständigen Behörden / Stellen von

Sozialistische Republik Vietnam

Es wird bescheinigt, dass der

Hersteller:

Qingdao Hightop Biotech Co., Ltd.
No.369 Hedong Road, Hi-tech Industrial Development Zone, 266112 Qingdao, Shandong, PEOPLE'S REPUBLIC OF CHINA

Bevollmächtigte:

MedNet EC-REP GmbH
Borkstrasse 10
48163 Münster
Deutschland

seine eingetragene Niederlassung in Deutschland hat und dass die gemäß der

**Verordnung (EU) 2017/746
vom 05. April 2017
über In-vitro-Diagnostika**

in der jeweils geltenden Fassung mit einem CE-Kennzeichen versehenen Produkte in der Union gehandelt werden dürfen:

Produkt/e:

Hepatitis-A-Virus-Antikörper-IgG/IgM-Schnelltest (Panel)
Nov GI+GII/Rov A/ADV Antigen-Schnelltest
Influenza A/Influenza B/ADV/RSV-Antigen-Schnelltest
EV71 IgM-Antikörper-Schnelltest
SARS-CoV-2/Flu A+B/AdV/RSV-Antigen-Schnelltest
Tests auf sexuell übertragbare Krankheiten
Urinalyse-Reagenzstreifen (Trockenchemieverfahren)

Free Sale Certificate

according to Article 55 even in conjunction with Article 110 para. 3 and para. 4 of Regulation (EU) 2017/746 and section 10 of the Medical Devices Law Implementing Act as amended

for presentation to the competent authorities / bodies of

Socialist Republic of Vietnam

It is also certified that the

Manufacturer:

Qingdao Hightop Biotech Co., Ltd.
No.369 Hedong Road, Hi-tech Industrial Development Zone, 266112 Qingdao, Shandong, PEOPLE'S REPUBLIC OF CHINA

Authorised Representative:

MedNet EC-REP GmbH
Borkstrasse 10
48163 Muenster
Germany

has its registered place of business in Germany and the devices bearing the CE marking in accordance with the

**Regulation (EU) 2017/746
of 05 April 2017
on in vitro diagnostic medical devices**

as amended may be marketed in the Union:

Product/s:

Hepatitis A Virus Antibody IgG/IgM Rapid Test (Panel)
Nov GI+GII/Rov A/ADV Antigen Rapid Test
Influenza A/Influenza B/ADV/RSV Antigen Rapid Test
EV71 IgM Antibody Rapid Test
SARS-CoV-2/Flu A+B/AdV/RSV Antigen Rapid Test
Sexually Transmitted Disease Tests
Urinalysis Reagent Strips (Dry Chemical Method)

Halbautomatischer Urinalysator

HIGHTOP Multi-Drogen-Urintest-Panel

Norovirus GI/GII Antigen-Schnelltest
(Immunochromatographie)

(siehe Anhang)

Münster, den 02.02.2026
Bezirksregierung Münster
Im Auftrag

(S. Sharples-Potthoff)



Semi-automatic Urine Analyzer

HIGHTOP Multi-Drug Urine Test Panel

Norovirus GI/GII Antigen Rapid Test
(Immunochromatography)

(see attachment)

Anlage 1 / Annex 1 FSC

| Artikel- oder Katalognummer / Article or catalogue number | Produktname / Device name | Basis-UDI-DI (gem. Art. 26 IVDR) / Basic-UDI-DI (acc. Art. 26 IVDR) | Nummer. der Bescheinigung der Benannten Stelle / Number of the certificate by the notified body, |
|---|--|---|--|
| 1 | Hepatitis A Virus Antibody IgG/IgM Rapid Test (Panel) Hepatitis A virus IgG/IgM antibody 1test/bag, 1test/kit, 20tests/kit, 25tests/kit, 40tests/kit | N/A | N/A |



Anlage 2 / Annex 2 FSC

| Artikel- oder Katalognummer / Article or catalogue number | Produktname / Device name | Basis-UDI-DI (gem. Art. 26 IVDR) / Basic-UDI-DI (acc. Art. 26 IVDR) | Nummer. der Bescheinigung der Benannten Stelle / Number of the certificate by the notified body, |
|---|---|---|--|
| 1 | Nov GI+GII/Rov A/ADV Antigen Rapid Test Norovirus GI+GII (Nov GI+GII), Rotavirus Group A (RovA) and the Enteric Adenovirus Type 40/41 (ADV) in human feces. Panel: 1test/kit, 20tests/kit | N/A | N/A |



Anlage 3 / Annex 3 FSC

| Artikel- oder Katalognummer / Article or catalogue number | Produktname / Device name | Basis-UDI-DI (gem. Art. 26 IVDR) / Basic-UDI-DI (acc. Art. 26 IVDR) | Nummer. der Bescheinigung der Benannten Stelle / Number of the certificate by the notified body, |
|---|--|---|--|
| 1 | Influenza A/Influenza B/ADV/RSV Antigen Rapid Test Influenza A/Influenza B/ADV/RSV Antigen 1test/bag, 1test/kit, 20tests/kit, 25tests/kit, 40tests/kit | N/A | N/A |



Anlage 4 / Annex 4 FSC

| Artikel- oder Katalognummer / Article or catalogue number | Produktname / Device name | Basis-UDI-DI (gem. Art. 26 IVDR) / Basic-UDI-DI (acc. Art. 26 IVDR) | Nummer. der Bescheinigung der Benannten Stelle / Number of the certificate by the notified body, |
|--|--|--|--|
| 1 | EV71 IgM Antibody Rapid Test EV71 IgM antibody in human serum/plasma/whole blood Cassette: 1test/kit, 25tests/kit, 40tests/kit | N/A | N/A |



Anlage 5 / Annex 5 FSC

| Artikel- oder Katalognummer / Article or catalogue number | Produktname / Device name | Basis-UDI-DI (gem. Art. 26 IVDR) / Basic-UDI-DI (acc. Art. 26 IVDR) | Nummer. der Bescheinigung der Benannten Stelle / Number of the certificate by the notified body, |
|---|---|---|--|
| 1 | SARS-CoV-2/Flu A+B/AdV/RSV Antigen Rapid Test SARS-CoV-2 Antigen, Flu A+B Antigen, AdV antigen, RSV antigen Panel: 1test/kit, 20tests/kit | N/A | N/A |



Anlage 6 / Annex 6 FSC

| Artikel- oder Katalognummer / Article or catalogue number | Produktname / Device name | Basis-UDI-DI (gem. Art. 26 IVDR) / Basic-UDI-DI (acc. Art. 26 IVDR) | Nummer. der Bescheinigung der Benannten Stelle / Number of the certificate by the notified body, |
|---|--|---|--|
| 1 | Neisseria Gonorrhoeae Antigen Rapid Test (Immunochromatography) Neisseria Gonorrhoeae Antigen Cassette: 1test/kit, 20tests/kit, 25tests/kit | N/A | N/A |
| 2 | Treponema Pallidum Antibody Rapid Test (Immunochromatography) Treponema Pallidum Antibody Strip: 1test/kit, 50tests/kit, 100tests/kit Cassette: 1test/kit, 25tests/kit, 40tests/kit | N/A | N/A |



Anlage 7 / Annex 7 FSC

| Artikel- oder Katalognummer / Article or catalogue number | Produktname / Device name | Basis-UDI-DI (gem. Art. 26 IVDR) / Basic-UDI-DI (acc. Art. 26 IVDR) | Nummer. der Bescheinigung der Benannten Stelle / Number of the certificate by the notified body, |
|---|--|---|--|
| 1 | Urinalysis Reagent Strips (Dry Chemical Method) Combinations: URS-1G (GLUCOSE) Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box Analyte: Glucose | N/A | N/A |
| 2 | Urinalysis Reagent Strips (Dry Chemical Method) Combinations: URS-1H (pH) Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box Analyte: pH | N/A | N/A |
| 3 | Urinalysis Reagent Strips (Dry Chemical Method) Combinations: URS-1K(KETONE) Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box Analyte: Ketone | N/A | N/A |
| 4 | Urinalysis Reagent Strips (Dry Chemical Method) Combinations: URS-1A(Ascorbic) Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box Analyte: Ascorbic | N/A | N/A |
| 5 | Urinalysis Reagent Strips (Dry Chemical Method) Combinations: URS-1L(LEUKOCYTES) | N/A | N/A |



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| | <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Leukocytes</p> | | |
| 6 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-1M (MICROALBUMINURIA)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Microalbuminuria</p> | N/A | N/A |
| 7 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-1Bi(BILIRUBIN)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Bilirubin</p> | N/A | N/A |
| 8 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-1Bi(BLOOD)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Blood</p> | N/A | N/A |
| 9 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-1S(SPECIFICGRAVITY)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Specific Gravity</p> | N/A | N/A |
| 10 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-1P(PROTEIN)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> | N/A | N/A |



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| | Analyte: Protein | | |
| 11 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-1N(NITRITE)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Nitrite</p> | N/A | N/A |
| 12 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-1U(UROBILINOGEN)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Urobilinogen</p> | N/A | N/A |
| 13 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-1Cr(CREATININE)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Creatinine</p> | N/A | N/A |
| 14 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-1Ca(CALCIUM)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Calcium</p> | N/A | N/A |
| 15 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-2K (GLUCOSE/KETONE)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Glucose, Ketone</p> | N/A | N/A |
| 16 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-2P (GLUCOSE/PROTEIN)</p> | N/A | N/A |



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| | <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Glucose, Protein</p> | | |
| 17 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-2N(LEU/NIT)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Leukocytes, Nitrite</p> | N/A | N/A |
| 18 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-2M(CR/MALB)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Creatinine, Microalbuminuria</p> | N/A | N/A |
| 19 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations:URS-2C(CR/Ca)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Creatinine, Calcium</p> | N/A | N/A |
| 20 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-2B(URO/BIL)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Urobilinogen, Bilirubin</p> | N/A | N/A |
| 21 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-3K (GLUCOSE/PROTEIN/KET)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> | N/A | N/A |



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| | Analyte: Glucose, Protein, Ketone | | |
| 22 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-3H (GLUCOSE/PROTEIN/pH)</p> <p>Kit size: 50T/canister, 100T/canister, 150T/canister, 200T/canister, 2T/box, 5T/box, 10T/box, 20T/box, 50T/box</p> <p>Analyte: Glucose, Protein, pH</p> | N/A | N/A |
| 23 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-4 (GLUCOSE/PROTEIN/pH/SG)</p> <p>Kit size: 50T/canister, 100T/canister, 150T/canister, 200T/canister, 2T/box, 5T/box, 10T/box, 20T/box, 50T/box</p> <p>Analyte: Glucose, Protein, pH, Specific Gravity</p> | N/A | N/A |
| 24 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-4B (GLUCOSE/PROTEIN/pH/Blood)</p> <p>Kit size: 50T/canister, 100T/canister, 150T/canister, 200T/canister, 2T/box, 5T/box, 10T/box, 20T/box, 50T/box</p> <p>Analyte: Glucose, Protein, pH, Blood</p> | N/A | N/A |
| 25 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-4P (LEUKOCYTES/NITRITES/Blood/PROTEIN)</p> <p>Kit size: 50T/canister, 100T/canister, 150T/canister, 200T/canister, 2T/box, 5T/box, 10T/box, 20T/box, 50T/box</p> <p>Analyte: Leukocytes, Nitrites, Blood, Protein</p> | N/A | N/A |
| 26 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-5 (GLU/PRO/pH/BLD/KET)</p> <p>Kit size: 50T/canister, 100T/canister, 150T/canister, 200T/canister, 2T/box, 5T/box, 10T/box, 20T/box, 50T/box</p> <p>Analyte: Glucose, Protein, pH, Blood, Ketone</p> | N/A | N/A |



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| 27 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-5H (GLU/PRO/KET/BLD/PH)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Glucose, Protein, Ketone, Blood, pH</p> | N/A | N/A |
| 28 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-9 (LEU/NIT/URO/PRO/pH/BLD/KET/BIL/GLU)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Ketone, Bilirubin, Glucose</p> | N/A | N/A |
| 29 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-10S (LEU/NIT/URO/PRO/pH/BLD/SG/KET/BIL/GLU)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, Glucose</p> | N/A | N/A |
| 30 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-10C (LEU/NIT/URO/PRO/pH/BLD/KET/BIL/GLU/VC)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Ketone, Bilirubin, Glucose, Ascorbic Acid</p> | N/A | N/A |
| 31 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-11</p> | N/A | N/A |



| | | | |
|----|---|-----|-----|
| | <p>(URO/BLD/BIL/KET/LEU/GLU/PRO/pH/NIT/SG/VC)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Urobilinogen, Blood, Bilirubin, Ketone, Leukocytes, Glucose, Protein, pH, Nitrite, Specific Gravity, Ascorbic Acid</p> | | |
| 32 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-12 (LEU/NIT/URO/PRO/pH/BLD/KET/BIL/GLU/SG/CR/CA)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Ketone, Bilirubin, Glucose, Specific Gravity, Creatinine and Calcium</p> | N/A | N/A |
| 33 | <p>Urinalysis Reagent Strips (Dry Chemical Method)</p> <p>Combinations: URS-14 (VC/LEU/GLU/MALB/BIL/pH/BLD/SG/KET/PRO/NIT/URO/CR/CA)</p> <p>Kit size: 50T/canister,100T/canister, 150T/canister,200T/canister,2T/box, 5T/box,10T/box, 20T/box, 50T/box</p> <p>Analyte: Ascorbic Acid, Leukocytes, Glucose, Microalbuminuria, Bilirubin, pH, Blood, Specific Gravity, Ketone, Protein, Nitrite, Urobilinogen, Creatinine and Calcium</p> | N/A | N/A |



Anlage 8 / Annex 8 FSC

| Artikel- oder Katalognummer / Article or catalogue number | Produktname / Device name | Basis-UDI-DI (gem. Art. 26 IVDR) / Basic-UDI-DI (acc. Art. 26 IVDR) | Nummer. der Bescheinigung der Benannten Stelle / Number of the certificate by the notified body, |
|---|--|---|--|
| 1 | Semi-automatic Urine Analyzer Analytes: Optical signal intensity Model: HT-115A The device is used together with urine analysis strips for semi-quantitative or qualitative detection of biochemical components in human urine samples. | 69350916HT202L X | N/A |

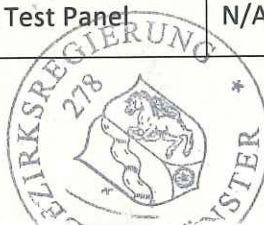


Anlage 9 / Annex 9 FSC

| Artikel- oder Katalognummer / Article or catalogue number | Produktname / Device name | Basis-UDI-DI (gem. Art. 26 IVDR) / Basic-UDI-DI (acc. Art. 26 IVDR) | Nummer. der Bescheinigung der Benannten Stelle / Number of the certificate by the notified body, |
|---|---|---|--|
| 1 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 2 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 2 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 3 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 3 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 4 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 4 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 5 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL</p> | N/A | N/A |



| | | | |
|---|---|-----|-----|
| | <p>SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | | |
| 5 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 6 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 6 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 7 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 7 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 8 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 8 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 9 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 9 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> | N/A | N/A |



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|----|--|-----|-----|
| | <p>Combinations: 10 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | | |
| 10 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 11 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 11 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 12 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 12 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 13 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 13 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 14 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> | N/A | N/A |



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|----|--|-----|-----|
| | <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | | |
| 14 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 15 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 15 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 16 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 16 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 17 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 17 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 18 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 18 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 19 in 1</p> | N/A | N/A |

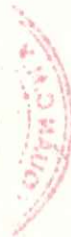


| | | | |
|----|--|-----|-----|
| | <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | | |
| 19 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 20 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 20 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 21 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |
| 21 | <p>HIGHTOP Multi-Drug Urine Test Panel</p> <p>Combinations: 22 in 1</p> <p>Analyte: OPI, MOP, BZO, MET, MDMA, PCP, THC, BAR, OXY, TCA, PPX, AMP, MTD, COC, BUP, EDDP, TML, K2, COT, FYL, SOMA, KET.</p> <p>Format: Panel</p> <p>Kit size: 20 tests/kit, 25 tests/kit</p> | N/A | N/A |



Anlage 10 / Annex 10 FSC

| Artikel- oder Katalognummer / Article or catalogue number | Produktname / Device name | Basis-UDI-DI (gem. Art. 26 IVDR) / Basic-UDI-DI (acc. Art. 26 IVDR) | Nummer. der Bescheinigung der Benannten Stelle / Number of the certificate by the notified body, |
|---|---|---|--|
| 1 | Norovirus GI/GII Antigen Rapid Test (Immunochromatography) Norovirus GI/GII antigen 1test/bag, 1test/kit, 20tests/kit, 25tests/kit, 40tests/kit | N/A | N/A |





Die Echtheit der umstehenden Unterschrift der
Mitarbeiterin der Bezirksregierung Münster
Frau Sharples-Potthoff
und die Echtheit des Dienstsiegels werden hiermit
beglaubigt. Gleichzeitig wird bescheinigt, dass die
Vorgenannte zur Ausstellung dieser Urkunde berechtigt
war.

Münster, 9. Februar 2026

Bezirksregierung Münster
Im Auftrag

Mapapa
Regierungsangestellte



ĐẠI SỨ QUÁN VIỆT NAM TẠI ĐỨC
CHỨNG NHẬN/ HỢP PHÁP HÓA LÃNH SỰ
KONSULARISCHE BEGLAUBIGUNG/LEGALISIERUNG

1. Quốc gia/Staat: **Việt Nam/Vietnam**

Giấy tờ, tài liệu này/Dieses Dokument

2. Với chữ ký của ông (bà)/U. von Herrn (Frau): **Mapapa**

3. Với chức danh/Funktion: **Viên chức**

4. Và con dấu của/Dienstiegel von: **Chính quyền quận Münster**
được chứng nhận/hợp pháp hóa lãnh sự/

wird hiermit konsularisch beglaubigt/legalisiert

5. Tại/in: **Berlin**

6. Ngày/Datum: **18/02/2026**

7. Cơ quan cấp/Ausgestellt von: **Đại sứ quán nước CHXHCN Việt Nam**
tại CHLB Đức Botschaft der SR Vietnam in der BR Deutschland

8. Số/Nr.: **43/LS-HPH/2026**

9. Ghi chú/Bemerkung: **Tem này không chứng nhận về nội dung và**
hình thức của giấy tờ, tài liệu/Dieser Stempel bestätigt weder den
Inhalt noch die Form der Urkunden und Unterlagen

TL/Đại sứ/ A. des Botschafters
Tham tán/Botschaftsrat

