



Bezirksregierung Münster

Bescheinigung der Verkehrsfähigkeit nach § 34 Abs. 1

der gegenwärtig gültigen Fassung des
Medizinproduktegesetzes (MPG)

zur Vorlage bei den zuständigen Behörden / Stellen von

Sozialistische Republik Vietnam

Es wird bescheinigt, dass die nachfolgend genannten
Medizinprodukte

- in Deutschland,
- in den Mitgliedstaaten der Europäischen Union und
- in den anderen Vertragsstaaten des Abkommens
über den Europäischen Wirtschaftsraum
uneingeschränkt verkehrsfähig sind.

Produkt / Produkte:

Drogen Missbrauchs Schnelltests, Tumormarker-Tests, HCG-
Tests, LH-Test, Infektionskrankheitstests, Urinalyse,
Fruchtbarkeits-Schwangerschaftstests, Entzündungsmarker-
Tests, Urinalysator, Chlamydien

Modellnamen / Katalognummern: siehe Anhang

Produktbeschreibung:

Drogen Missbrauchs Schnelltests - Schnelle
chromatographische Immunoassay für den Nachweis von
Drogenmissbrauch in menschlichen Proben
Tumormarker-Tests - Schnelle Immunoassays zum Nachweis
von Tumormarkern in menschlichen Proben zur Unterstützung
der Krebsdiagnose
HCG-Tests - Schnelltest
LH-Test - Schnelltest
Infektionskrankheitstests - Schnelle chromatographische
Immunoassays zur Bestimmung von Infektionsmarkern durch
Untersuchung von menschlichen Proben.
Urinalyse - URINE MULTI-CONSTITUENT TEST STRIPS
Fruchtbarkeits-Schwangerschaftstests - SONSTIGE
FERTILITÄT / Schwangerschaftsschnelltest
Entzündungsmarker-Tests - Schnelle Tests als Hilfe bei der
Diagnose von Entzündungserkrankungen durch den Nachweis
Serum Amyloid A (SAA) und/oder C-reaktives Protein (CRP)
oder Lactoferrin oder Procalcitonin (PCT) oder Calprotectin in
menschlichen Proben
Urinalysator - Urin Analyzer ist eine semi quantitative
Bewertung von Urin mit Hilfe von trockenen chemischen
Methoden. Entsprechend das Prinzip der photoelektrischen
Kolorimetrie, Urin-Analysator wird verwendet, um den Inhalt der
biochemischen bewerten Bestandteile im Urin.
Chlamydien - CHLAMYDIA AG - Schnelltest

Hersteller:

Hangzhou AllTest Biotech Co., Ltd.
550 Yin Hai Street, Hangzhou Economic and Technological
Development Area
310018 Hangzhou
P. R. China

Certificate of Marketability according to § 34 (1)

of the Medical Devices Law (MPG)
in the current valid version

for presentation to the competent authorities / bodies of

Socialist Republic of Vietnam

It is certified that the following medical devices can be marketed
without restriction within

- Germany,
- the member states of the European Union and
- the other states having a contractual agreement with
the European Economic Area.

Product / Products:

Drugs of Abuse Rapid Tests, Tumor marker tests, HCG Tests,
LH Test, Infection Disease Tests, Urinalysis, FERTILITY
PREGNANCY Tests, Inflammatory marker tests, Urine
Analyser, Chlamydia


Model names / catalogue numbers: see attachment.

Product description:

Drugs of Abuse Rapid Tests - Rapid chromatographic
immunoassay for the detection of drugs abuse in human
specimen
Tumor marker tests - Rapid immunoassays for the detection of
tumor markers in human specimen to aid in the diagnosis of
cancer
HCG Tests - RAPID Test
LH Test - RAPID Test
Infection Disease Tests - Rapid chromatographic
immunoassays for determination of infection markers by
investigating human specimen.
Urinalysis - URINE MULTI-CONSTITUENT TEST STRIPS
FERTILITY PREGNANCY Tests - OTHER FERTILITY /
PREGNANCY RAPID TESTS
Inflammatory marker tests - Rapid tests as an aid in the
diagnosis of inflammatory conditions by detecting Serum
Amyloid A (SAA) or/and C-reactive protein (CRP) or Lactoferrin
or Procalcitonin (PCT) or Calprotectin in human specimen.
Urine Analyser - Urine Analyzer is a semi quantitative
assessment of urine by using dry chemical methods. According
to the principle of photoelectric colorimetry, urine analyzer is
used to evaluate the content of biochemical components in the
urine.
Chlamydia - CHLAMYDIA AG - RAPID TEST

Manufacturer:

Hangzhou AllTest Biotech Co., Ltd.
550 Yin Hai Street, Hangzhou Economic and Technological
Development Area
310018 Hangzhou
P. R. China

<p>Der für das erstmalige Inverkehrbringen auf dem EWG Markt Verantwortliche:</p> <p>MedNet GmbH Borkstrasse 10 48163 Münster Deutschland</p> <p>Es wird auch bescheinigt, dass der Hersteller durch das CE-Kennzeichen zum Ausdruck bringt, dass das Medizinprodukt die Grundlegenden Anforderungen der</p> <p style="text-align: center;">Richtlinie des Europäischen Parlamentes und des Rates vom 27.10.1998 98/79/EG</p> <p>in der gegenwärtig gültigen Fassung erfüllen und das vorgeschriebene Konformitätsbewertungsverfahren durchgeführt wurde.</p> <p>Bezirksregierung Münster -Dezernat 24.6. – 48128 Münster, 25.05.2020 Im Auftrag</p>  <p>(Dr. Terhechte)</p>	<p>Those responsible for first placing the product on the EEA market:</p> <p>MedNet GmbH Borkstrasse 10 48163 Münster Germany</p> <p>It is also certified that the manufacturer with the CE-mark confirms that the medical devices fulfill the essential requirements of the</p> <p style="text-align: center;">Directive of the European Parliament and the Council of 27 October 1998 98/79/EC</p> <p>in the current valid version and that the required conformity assessment has been completed.</p>
<p>Fachauskunft</p>	<p>Expertise</p>
<p>Die in der Anlage genannten Produkte werden als Medizinprodukte hergestellt und in den Verkehr gebracht. Die Voraussetzungen dazu sind in der Europäischen Richtlinie 98/79/EWG und dem Medizinproduktegesetz der Bundesrepublik Deutschland geregelt. Die bisherige Herstellung der o.g. Produkte entsprechend den GMP-Forderungen in der Europäischen Union wird dadurch fortgeführt, da eines der wesentlichen Ziele der Richtlinie 98/79/EWG die Aufrechterhaltung bzw. Verbesserung des in den Mitgliedsstaaten erreichten Gesundheitsschutzniveaus ist.</p>	<p>The enclosed listed products are manufactured and placed on the market as medical devices. The respective requirements are regulated in the European directive 98/79/EWG and the Medical Device Law of the Federal Republic of Germany. The hitherto manufacture of the a.m. products according to GMP requirements in the European Union is hereby continued, since maintenance and improvement, respectively, of the health protection level attained in the member states is one of the main objectives of directive 98/79/EWG.</p>

Registration Number DE	Short Description	Product Name	Catalogue Number
DE/CA22/419-810.1-IVD	Rapid chromatographic immunoassay for the detection of drugs abuse in human specimen	Acetaminophen (ACE) Rapid Test Cassette	DAC-102
		Acetaminophen (ACE) Rapid Test Panel	DAC-114
		Acetaminophen (ACE) Rapid Test Dipstick	DAC-101
		Amphetamine (AMP) Rapid Test Cassette	DAM-102
		Amphetamine (AMP) Rapid Test Panel	DAM-114
		Amphetamine (AMP) Rapid Test Dipstick	DAM-101
		Barbiturate (BAR) Rapid Test Cassette	DRA-102
		Barbiturate (BAR) Rapid Test Panel	DBA-114
		Barbiturate (BAR) Rapid Test Dipstick	DBA-101
		Buprenorphine (BUP) Rapid Test Cassette	DBU-102
		Buprenorphine (BUP) Rapid Test Panel	DBU-114
		Buprenorphine (BUP) Rapid Test Dipstick	DBU-101
		Benzodiazepines (BZO) Rapid Test Cassette	DBZ-102
		Benzodiazepines (BZO) Rapid Test Panel	DBZ-114
		Benzodiazepines (BZO) Rapid Test Dipstick	DBZ-101
		Clonazepam (CLO) Rapid Test Cassette	DCL-102
		Clonazepam (CLO) Rapid Test Panel	DCL-114
		Clonazepam (CLO) Rapid Test Dipstick	DCL-101
		COCAINE (COC) Rapid Test Cassette	DCO-102
		COCAINE (COC) Rapid Test Panel	DCO-114
		COCAINE (COC) Rapid Test Dipstick	DCO-101
		Cotinine (COT) Rapid Test Cassette	DCT-102
		Cotinine (COT) Rapid Test Panel	DCT-114
		Cotinine (COT) Rapid Test Dipstick	DCT-101
		Diazepam (DIA) Rapid Test Cassette	DDI-102
		Diazepam (DIA) Rapid Test Panel	DDI-114
		Diazepam (DIA) Rapid Test Dipstick	DDI-101
		Ethylenediamine dimethylphosphinic acid (EDDP) Rapid Test Cassette	DED-102
		Ethylenediamine dimethylphosphinic acid (EDDP) Rapid Test Panel	DED-114
		Ethylenediamine dimethylphosphinic acid (EDDP) Rapid Test Dipstick	DED-101
		Ethyl Glucuronide (ETG) Rapid Test Cassette	DET-102
		Ethyl Glucuronide (ETG) Rapid Test Panel	DET-114
		Ethyl Glucuronide (ETG) Rapid Test Dipstick	DET-101
		Fentanyl (FYL) Rapid Test Cassette	DFY-102
		Fentanyl (FYL) Rapid Test Panel	DFY-114
		Fentanyl (FYL) Rapid Test Dipstick	DFY-101
		Ketamine (KET) Rapid Test Cassette	DKE-102
		Ketamine (KET) Rapid Test Panel	DKE-114
		Ketamine (KET) Rapid Test Dipstick	DKE-101
		6-Monoacetylmorphine (6-MAM) Rapid Test Cassette	DMA-102
		6-Monoacetylmorphine (6-MAM) Rapid Test Panel	DMA-114
		6-Monoacetylmorphine (6-MAM) Rapid Test Dipstick	DMA-101
		Ecstasy (MDMA) Rapid Test Cassette	DMD-102
		Ecstasy (MDMA) Rapid Test Panel	DMD-114
		Ecstasy (MDMA) Rapid Test Dipstick	DMD-101
		Tenamfetamine (MDA) Rapid Test Cassette	DMDA-102
		Tenamfetamine (MDA) Rapid Test Panel	DMDA-114
		Tenamfetamine (MDA) Rapid Test Dipstick	DMDA-101
		Methylenedioxypropiovalerone (MDPV) Rapid Test Cassette	DMDP-102
		Methylenedioxypropiovalerone (MDPV) Rapid Test Panel	DMDP-114
		Methylenedioxypropiovalerone (MDPV) Rapid Test Dipstick	DMDP-101
		Methylphenidate (MPD) Rapid Test Cassette	DMP-102
		Methylphenidate (MPD) Rapid Test Panel	DMP-114
		Methylphenidate (MPD) Rapid Test Dipstick	DMP-101
		Methamphetamine (MET) Rapid Test Cassette	DME-102
		Methamphetamine (MET) Rapid Test Panel	DME-114
		Methamphetamine (MET) Rapid Test Dipstick	DME-101
		Morphine (MOP) Rapid Test Cassette	DMO-102
		Morphine (MOP) Rapid Test Panel	DMO-114
		Morphine (MOP) Rapid Test Dipstick	DMO-101
		Methaqualone (MQL) Rapid Test Cassette	DMQ-102
		Methaqualone (MQL) Rapid Test Panel	DMQ-114
		Methaqualone (MQL) Rapid Test Dipstick	DMQ-101
		Methadone (MTD) Rapid Test Cassette	DMT-102
		Methadone (MTD) Rapid Test Panel	DMT-114
		Methadone (MTD) Rapid Test Dipstick	DMT-101
		Opiates (OPI) Rapid Test Cassette	DOP-102
		Opiates (OPI) Rapid Test Panel	DOP-114
		Opiates (OPI) Rapid Test Dipstick	DOP-101
		Oxycodone (OXY) Rapid Test Cassette	DOX-102
		Oxycodone (OXY) Rapid Test Panel	DOX-114
		Oxycodone (OXY) Rapid Test Dipstick	DOX-101
		Phencyclidine (PCP) Rapid Test Cassette	DPC-102
		Phencyclidine (PCP) PCP Rapid Test Panel	DPC-114
		Phencyclidine (PCP) PCP Rapid Test Dipstick	DPC-101
		Propoxyphene (PPX) Rapid Test Cassette	DPP-102
		Propoxyphene (PPX) Rapid Test Panel	DPP-114
		Propoxyphene (PPX) Rapid Test Dipstick	DPP-101
		Synthetic Marijuana (K2) Rapid Test Cassette	DSM-102
		Synthetic Marijuana (K2) Rapid Test Panel	DSM-114
		Synthetic Marijuana (K2) Rapid Test Dipstick	DSM-101
		Tricyclic Antidepressants (TCA) Rapid Test Cassette	DTC-102
		Tricyclic Antidepressants (TCA) Rapid Test Panel	DTC-114
		Tricyclic Antidepressants (TCA) Rapid Test Dipstick	DTC-101

Marijuana (THC) Rapid Test Cassette	DTH-102
Marijuana (THC) Rapid Test Panel	DTH-114
Marijuana (THC) Rapid Test Dipstick	DTH-101
Tramadol (TML) Rapid Test Cassette	DTM-102
Tramadol (TML) Rapid Test Panel	DTM-114
Tramadol (TML) Rapid Test Dipstick	DTM-101
Lysergic Acid Diethylamide (LSD) Rapid Test Cassette	DLS-102
Lysergic Acid Diethylamide (LSD) Rapid Test Panel	DLS-114
Lysergic Acid Diethylamide (LSD) Rapid Test Dipstick	DLS-101
Zolpidem (ZOL) Rapid Test Cassette	DZO-102
Zolpidem (ZOL) Rapid Test Panel	DZO-114
Zolpidem (ZOL) Rapid Test Dipstick	DZO-101
Multi-Drug 2 Drugs Rapid Test Cassette	DOA-125
Multi-Drug 3 Drugs Rapid Test Cassette	DOA-135
Multi-Drug 4 Drugs Rapid Test Cassette	DOA-145
Multi-Drug 5 Drugs Rapid Test Cassette	DOA-155
Multi-Drug 6 Drugs Rapid Test Cassette	DOA-165
Multi-Drug 7 Drugs Rapid Test Cassette	DOA-175
Multi-Drug 8 Drugs Rapid Test Cassette	DOA-185
Multi-Drug 9 Drugs Rapid Test Cassette	DOA-195
Multi-Drug 10 Drugs Rapid Test Cassette	DOA-1105
Multi-Drug 11 Drugs Rapid Test Cassette	DOA-1115
Multi-Drug 12 Drugs Rapid Test Cassette	DOA-1125
Multi-Drug 2 Drugs Rapid Test Panel	DOA-124
Multi-Drug 3 Drugs Rapid Test Panel	DOA-134
Multi-Drug 4 Drugs Rapid Test panel	DOA-144
Multi-Drug 5 Drugs Rapid Test panel	DOA-154
Multi-Drug 6 Drugs Rapid Test panel	DOA-164
Multi-Drug 7 Drugs Rapid Test panel	DOA-174
Multi-Drug 8 Drugs Rapid Test panel	DOA-184
Multi-Drug 9 Drugs Rapid Test panel	DOA-194
Multi-Drug 10 Drugs Rapid Test panel	DOA-1104
Multi-Drug 11 Drugs Rapid Test panel	DOA-1114
Multi-Drug 12 Drugs Rapid Test panel	DOA-1124
Multi-Drug 13 Drugs Rapid Test Panel	DOA-1134
Multi-Drug 14 Drugs Rapid Test Panel	DOA-1144
Multi-Drug 15 Drugs Rapid Test Panel	DOA-1154
Multi-Drug 16 Drugs Rapid Test Panel	DOA-1164
Multi-Drug 2 Drugs Rapid Test 1-Step Cup	DOA-127-A
Multi-Drug 3 Drugs Rapid Test 1-Step Cup	DOA-137-A
Multi-Drug 4 Drugs Rapid Test 1-Step Cup	DOA-147-A
Multi-Drug 5 Drugs Rapid Test 1-Step Cup	DOA-157-A
Multi-Drug 6 Drugs Rapid Test 1-Step Cup	DOA-167-A
Multi-Drug 7 Drugs Rapid Test 1-Step Cup	DOA-177-A
Multi-Drug 8 Drugs Rapid Test 1-Step Cup	DOA-187-A
Multi-Drug 9 Drugs Rapid Test 1-Step Cup	DOA-197-A
Multi-Drug 10 Drugs Rapid Test 1-Step Cup	DOA-1107-A
Multi-Drug 11 Drugs Rapid Test 1-Step Cup	DOA-1117-A
Multi-Drug 12 Drugs Rapid Test 1-Step Cup	DOA-1127-A
Multi-Drug 2 Drugs Rapid Test 2-Step Cup	DOA-127-B
Multi-Drug 3 Drugs Rapid Test 2-Step Cup	DOA-137-B
Multi-Drug 4 Drugs Rapid Test 2-Step Cup	DOA-147-B
Multi-Drug 5 Drugs Rapid Test 2-Step Cup	DOA-157-B
Multi-Drug 6 Drugs Rapid Test 2-Step Cup	DOA-167-B
Multi-Drug 7 Drugs Rapid Test 2-Step Cup	DOA-177-B
Multi-Drug 8 Drugs Rapid Test 2-Step Cup	DOA-187-B
Multi-Drug 9 Drugs Rapid Test 2-Step Cup	DOA-197-B
Multi-Drug 10 Drugs Rapid Test 2-Step Cup	DOA-1107-B
Multi-Drug 11 Drugs Rapid Test 2-Step Cup	DOA-1117-B
Multi-Drug 12 Drugs Rapid Test 2-Step Cup	DOA-1127-B
Adulteration Strip (accessory of the multidrug test)	DAT-111
Methcathinone Rapid Test Cassette	DMCA-102
Methcathinone Rapid Test Panel	DMCA-114
Methcathinone Rapid Test Dipstick	DMCA-101
Tropicamide (TROP) Rapid Test Dipstick	DTRO-101
Tropicamide (TROP) Rapid Test Cassette	DTRO-102
Tropicamide (TROP) Rapid Test Panel	DTRO-114
Alprazolam (ALP) Rapid Test Dipstick	DALP-101
Alprazolam (ALP) Rapid Test Cassette	DALP-102
Alprazolam (ALP) Rapid Test Panel	DALP-114
Zopiclone (ZOP) Rapid Test Dipstick	DZOP-101
Zopiclone (ZOP) Rapid Test Cassette	DZOP-102
Zopiclone (ZOP) Rapid Test Panel	DZOP-114
Carfentanyl (CFYL) Rapid Test Dipstick	DCFY-101
Carfentanyl (CFYL) Rapid Test Cassette	DCFY-102
Carfentanyl (CFYL) Rapid Test Panel	DCFY-114
7-Aminoclonazepam (ACL) Rapid Test Cassette	DACL-102
7-Aminoclonazepam (ACL) Rapid Test Panel	DACL-114
7-Aminoclonazepam (ACL) Rapid Test Dipstick	DACL-101
Alcohol Rapid Test Cassette	DAL-102
Alcohol Rapid Test Panel	DAL-114
Alcohol Rapid Test Dipstick	DAL-101
Alcohol Rapid Test Dipstick	DAL-801
Alcohol Rapid Test Cassette	DAL-802
Caffeine (CAF) Rapid Test Cassette	DCAF-102
Caffeine (CAF) Rapid Test Panel	DCAF-114
Caffeine (CAF) Rapid Test Dipstick	DCAF-101
Cathinon (CAT) Rapid Test Cassette	DCA-102
Cathinon (CAT) Rapid Test Panel	DCA-114

Cathinon (CAT) Rapid Test Dipstick	DCA-101
Pregabalin (PGB) Rapid Test Cassette	DPG-102
Pregabalin (PGB) Rapid Test Panel	DPG-114
Pregabalin (PGB) Rapid Test Dipstick	DPG-101
Colinine (COT) Rapid Test Midstream	DCT-803
Marijuana (THC) Rapid Test Midstream	DTH-803
Multi-Drug 2 Drugs Rapid Test Midstream	DSD-823-A
Multi-Drug 3 Drugs Rapid Test Midstream	DSD-833-A
Multi-Drug 4 Drugs Rapid Test Midstream	DSD-843-A
Multi-Drug 5 Drugs Rapid Test Midstream	DSD-853-A
Multi-Drug 6 Drugs Rapid Test Midstream	DSD-863-A
Multi-Drug 2 Drugs Rapid Test Midstream	DSD-823-B
Multi-Drug 3 Drugs Rapid Test Midstream	DSD-833-B
Multi-Drug 4 Drugs Rapid Test Midstream	DSD-843-B
Multi-Drug 5 Drugs Rapid Test Midstream	DSD-853-B
Multi-Drug 6 Drugs Rapid Test Midstream	DSD-863-B
Multi-Drug 7 Drugs Rapid Test Midstream	DSD-873-B
Multi-Drug 8 Drugs Rapid Test Midstream	DSD-883-B
Multi-Drug 9 Drugs Rapid Test Midstream	DSD-893-B
Multi-Drug 2 Drugs Rapid Test Cup	DSD-827
Multi-Drug 3 Drugs Rapid Test Cup	DSD-837
Multi-Drug 4 Drugs Rapid Test Cup	DSD-847
Multi-Drug 5 Drugs Rapid Test Cup	DSD-857
Multi-Drug 6 Drugs Rapid Test Cup	DSD-867
Multi-Drug 7 Drugs Rapid Test Cup	DSD-877
Multi-Drug 8 Drugs Rapid Test Cup	DSD-887
Multi-Drug 9 Drugs Rapid Test Cup	DSD-897
Multi-Drug 10 Drugs Rapid Test Cup	DSD-8107
Multi-Drug 11 Drugs Rapid Test Cup	DSD-8117
Multi-Drug 12 Drugs Rapid Test Cup	DSD-8127
Colinine (COT) Rapid Test Panel	DCT-X14
Multi-Drug 2 Drugs Rapid Test Panel	DOA-X24
Multi-Drug 3 Drugs Rapid Test Panel	DOA-X34
Multi-Drug 4 Drugs Rapid Test Panel	DOA-X44
Multi-Drug 5 Drugs Rapid Test Panel	DOA-X54
Multi-Drug 6 Drugs Rapid Test Panel	DOA-X64
Multi-Drug 7 Drugs Rapid Test Panel	DOA-X74
Multi-Drug 8 Drugs Rapid Test Panel	DOA-X84
Multi-Drug 9 Drugs Rapid Test Panel	DOA-X94
Multi-Drug 10 Drugs Rapid Test Panel	DOA-X104
Multi-Drug 11 Drugs Rapid Test Panel	DOA-X114
Multi-Drug 12 Drugs Rapid Test Panel	DOA-X124
COT Rapid Test Cassette	DCT-402
Multi-drug 2 drugs Test Cassette	DOA-425
Multi-drug 3 drugs Test Cassette	DOA-435
Multi-drug 4 drugs Test Cassette	DOA-445
Multi-drug 5 drugs Test Cassette	DOA-455
Multi-drug 6 drugs Test Cassette	DOA-465
Multi-drug 7 drugs Test Cassette	DOA-475
Multi-drug 8 drugs Test Cassette	DOA-485
Multi-drug 9 drugs Test Cassette	DOA-495
Multi-drug 10 drugs Test Cassette	DOA-4105
Multi-drug 11 drugs Test Cassette	DOA-4115
Multi-drug 12 drugs Test Cassette	DOA-4125
AB-PINACA (ABP) Rapid Test Cassette	DABP-102
AB-PINACA (ABP) Rapid Test Panel	DABP-114
AB-PINACA (ABP) Rapid Test Dipstick	DABP-101
α -Pyrrolidinovaleerophenone (α -PVP) Rapid Test Cassette	DAP-102
α -Pyrrolidinovaleerophenone (α -PVP) Rapid Test Panel	DAP-114
α -Pyrrolidinovaleerophenone (α -PVP) Rapid Test Dipstick	DAP-101
γ -Hydroxybutyric acid (GHB) Rapid Test Cassette	DGHB-102
Mephedrone HCl (MEP) Rapid Test Cassette	DMEP-102
Mephedrone HCl (MEP) Rapid Test Panel	DMEP-114
Mephedrone HCl (MEP) Rapid Test Dipstick	DMEP-101
Oral Fluid Multi-Drug 2 Drugs Test A Cassette	DSD-825-A
Oral Fluid Multi-Drug 3 Drugs Test A Cassette	DSD-835-A
Oral Fluid Multi-Drug 4 Drugs Test A Cassette	DSD-845-A
Oral Fluid Multi-Drug 5 Drugs Test A Cassette	DSD-855-A
Oral Fluid Multi-Drug 6 Drugs Test A Cassette	DSD-865-A
Oral Fluid Multi-Drug 7 Drugs Test A Cassette	DSD-875-A
Oral Fluid Multi-Drug 8 Drugs Test A Cassette	DSD-885-A
Oral Fluid Multi-Drug 9 Drugs Test A Cassette	DSD-895-A
Cannabinol (CNB) Rapid Test Cassette	DCNB-102
Cannabinol (CNB) Rapid Test Panel	DCNB-114
Cannabinol (CNB) Rapid Test Dipstick	DCNB-101
Gabapentin (GAR) Rapid Test Cassette	DGAB-102
Gabapentin (GAR) Rapid Test Panel	DGAB-114
Gabapentin (GAR) Rapid Test Dipstick	DGAB-101
Meperidine (MPRD) Rapid Test Cassette	DMPR-102
Meperidine (MPRD) Rapid Test Panel	DMPR-114
Meperidine (MPRD) Rapid Test Dipstick	DMPR-101
Trazodone (TZD) Rapid Test Cassette	DTZD-102
Trazodone (TZD) Rapid Test Panel	DTZD-114
Trazodone (TZD) Rapid Test Dipstick	DTZD-101
Zaleplon (ZAL) Rapid Test Cassette	DZAL-102
Zaleplon (ZAL) Rapid Test Panel	DZAL-114
Zaleplon (ZAL) Rapid Test Dipstick	DZAL-101
Mescaline (MES) Rapid Test Dipstick	DMES-101/111
Mescaline (MES) Rapid Test Cassette	DMES-102

Mescaline (MES) Rapid Test Panel	DMFS-114
UR-144 ((1-pentyl-1H-indol-3-yl) (2,2,3,3-tetramethylcyclopropyl) methanone) Rapid Test Dipstick	DUR-101/111
UR-144 ((1-pentyl-1H-indol-3-yl) (2,2,3,3-tetramethylcyclopropyl) methanone) Rapid Test Cassette	DUR-102
UR-144 ((1-pentyl-1H-indol-3-yl) (2,2,3,3-tetramethylcyclopropyl) methanone) Rapid Test Panel	DUR-114
MULTI-DRUG 12 DRUGS RAPID TEST CUP	DOA A1127C-025-A3
Fluoxetine (FLX) Rapid Test Cassette	DFLX-102
Fluoxetine (FLX) Rapid Test Panel	DFLX-114
Fluoxetine (FLX) Rapid Test Dipstick	DFLX-101
Tilidine (TLD) Rapid Test Cassette	DTLD-102
Tilidine (TLD) Rapid Test Panel	DTLD-114
Tilidine (TLD) Rapid Test Dipstick	DTLD-101
Marijuana (THC) Parent Rapid Test Cassette	DTH-P802
Barbiturate (BAR) Rapid Test Cassette(for Reader)	DBA-R102
Benzodiazepines (BZO) Rapid Test Cassette(for Reader)	DBZ-R102
COCAINE (COC) Rapid Test Cassette(for Reader)	DCO-R102
Ethyl Glucuronide (ETG) Rapid Test Cassette(for Reader)	DET-R102
Ketamine (KET) Rapid Test Cassette(for Reader)	DKE-R102
Methylenedioxy-methamphetamine (MDMA) Rapid Test Cassette(for Reader)	DMD-R102
Methadone (MTD) Rapid Test Cassette(for Reader)	DMT-R102
Synthetic Marijuana (K2) Rapid Test Cassette(for Reader)	DSM-R102
Marijuana (THC) Rapid Test Cassette(for Reader)	DTH-R102
Multi-Drug 3 Drugs Rapid Test Panel(for Reader)	DOA-R134
Multi-Drug 4 Drugs Rapid Test panel(for Reader)	DOA-R144
Multi-Drug 5 Drugs Rapid Test panel(for Reader)	DOA-R154
Multi-Drug 6 Drugs Rapid Test panel(for Reader)	DOA-R164
Multi-Drug 7 Drugs Rapid Test panel(for Reader)	DOA-R174
Multi-Drug 8 Drugs Rapid Test panel(for Reader)	DOA-R184
Multi-Drug 9 Drugs Rapid Test panel(for Reader)	DOA-R194
Multi-Drug 10 Drugs Rapid Test panel(for Reader)	DOA-R1104
Multi-Drug 12 Drugs Rapid Test panel(for Reader)	DOA-R1124
Multi-Drug 3 Drugs Rapid Test Panel with Adulteration(for Reader)	DUA-R134
Multi-Drug 4 Drugs Rapid Test Panel with Adulteration(for Reader)	DUA-R144
Multi-Drug 5 Drugs Rapid Test Panel with Adulteration(for Reader)	DUA-R154
Multi-Drug 6 Drugs Rapid Test Panel with Adulteration(for Reader)	DUA-R164
Multi-Drug 7 Drugs Rapid Test Panel with Adulteration(for Reader)	DUA-R174
Multi-Drug 8 Drugs Rapid Test Panel with Adulteration(for Reader)	DUA-R184
Multi-Drug 9 Drugs Rapid Test Panel with Adulteration(for Reader)	DUA-R194
Multi-Drug 10 Drugs Rapid Test Panel with Adulteration(for Reader)	DUA-R1104
Multi-Drug 12 Drugs Rapid Test Panel with Adulteration(for Reader)	DUA-R1124
Multi-Drug 3 Drugs Rapid Test Cassette(for Reader)	DOA-R135
Multi-Drug 5 Drugs Rapid Test Cassette(for Reader)	DOA-R155
Multi-Drug 6 Drugs Rapid Test Cassette(for Reader)	DOA-R165
Multi-Drug 7 Drugs Rapid Test Cassette(for Reader)	DOA-R175
Multi-Drug 12 Drugs Rapid Test Cassette(for Reader)	DOA-R1125

Sonstige Produkte / Other Devices

Registration Number DE	Short Description	Product Name	Catalogue Number
DE/CA22/419-815.2-IVD	Rapid immunoassays for the detection of tumor markers in human specimen to aid in the diagnosis of cancer	AFP(α -fetoprotein) Rapid Test Cassette	TAF-402
		CEA (Carcino-embryonic antigen) Rapid Test Cassette	TCE-402
		FOB (Feces Occult Blood) Rapid Test Cassette	TFO-602
		FOB (Feces Occult Blood) Rapid Test Dipstick	TFO-601
		Transferrin and FOB Combo Rapid Test Cassette	TTFC-625
		Hb+Hp/Hb Combo Rapid Test Cassette	THPB-625
		Transferrin/FOB and Hb-Hp Combo Rapid Test Cassette	TTFH-635
		CA125 Rapid Test Cassette	T125-402
		CA15-3 Rapid Test Cassette	T153-402
		CA19-9 Rapid Test Cassette	T199-402
		CEA (Carcino-embryonic antigen) Test Cassette (for Analyzer)	FI-CEA-302
		AFP (α -fetoprotein) Test Cassette (for Analyzer)	FI-AFP-302
		Calprotectin and FOB Combo Rapid Test Cassette	TCFC-625
		FOB Rapid Test Cassette (for Reader)	TFO-R602

Sonstige Produkte / Other Devices

Registration Number DE	EDMA code	Product Name	Catalogue Number
DE/CA22/419-817-IVD	12 70 05 04 00	Ovulation (LH) Rapid Test Dipstick	FLH-101
		Ovulation (LH) Enhanced Sensitivity Rapid Test Dipstick	FLH-U101
		Ovulation (LH) Rapid Test Cassette	FLH-102
		Ovulation (LH) Enhanced Sensitivity Rapid Test Cassette	FLH-U102
		Ovulation (LH) Rapid Test Dipstick (Canister Pack)	FLH-111
		Ovulation (LH) Enhanced Sensitivity Rapid Test Dipstick (Canister Pack)	FLH-U111
		Ovulation (LH) Rapid Test Midstream	FLH-103
		Ovulation (LH) Rapid Test Midstream	FLH-M103
		Ovulation (LH) Enhanced Sensitivity Rapid Test Midstream	FLH-U103

Sonstige Produkte / Other Devices

Registration Number DE	EDMA code	Product Name	Catalogue Number
DE/CA22/419-818-IVD	12 70 05 02 00	Pregnancy (hCG) (Human Chorionic Gonadotropin) Rapid Test Dipstick	FHC-101
		Pregnancy (hCG) (Human Chorionic Gonadotropin) Enhanced Sensitivity Rapid Test Dipstick	FHC-U101
		Pregnancy (hCG) (Human Chorionic Gonadotropin) Rapid Test Cassette	FHC-102
		Pregnancy (hCG) (Human Chorionic Gonadotropin) Enhanced Sensitivity Rapid Test Cassette	FHC-U102
		Pregnancy (hCG) (Human Chorionic Gonadotropin) Rapid Test Dipstick (Canister Pack)	FHC-111
		Pregnancy (hCG) (Human Chorionic Gonadotropin) Enhanced Sensitivity Rapid Test Dipstick (Canister Pack)	FHC-U111
		Pregnancy (hCG) Rapid Test Cassette	FHC-402
		Pregnancy (hCG) Rapid Test Cassette	FHC-202
		Pregnancy (hCG) Enhanced Sensitivity Rapid Test Cassette	FHC-U202
		Pregnancy (hCG) Rapid Test Dipstick	FHC-201
		Pregnancy (hCG) Enhanced Sensitivity Rapid Test Dipstick	FHC-U201
		Pregnancy (hCG) Rapid Test Dipstick (Canister Pack)	FHC-211
		Pregnancy (hCG) Enhanced Sensitivity Rapid Test Dipstick (Canister Pack)	FHC-U211
		Pregnancy (hCG) Rapid Test Midstream	FHC-103
		Pregnancy (hCG) Rapid Test Midstream	FHC-F103
		Pregnancy (hCG) Enhanced Sensitivity Rapid Test Midstream	FHC-U103
		Pregnancy (hCG) Enhanced Sensitivity Rapid Test Cassette	FHC-U402
		Pregnancy (hCG) Rapid Test Cassette (for Reader)	FHC-R102
		β -HCG Test Cassette (for Analyzer)	FI-BHCG-302

Registration Number DE	Short Description	Product Name	Catalogue Number
DF/CA22/419-R22 3-ND	Rapid chromatographic immunoassays for determination of infection markers by investigating human specimen.	Adenovirus Rapid Test Cassette	IAD-602
		Adenovirus pneumonia Antigen Rapid Test Cassette	IAD-502
		Chagas Rapid Test Cassette	ICHA-402
		Chagas Rapid Test Cassette	ICHA-302
		Chikungunya IgG/IgM Rapid Test Cassette	ICHI-402
		Chikungunya IgG/IgM Rapid Test Cassette	ICHI-302
		Dengue Combo Rapid Test Cassette	IDEC-425
		Dengue IgG/IgM Rapid Test Cassette	IDEN-402
		Dengue NS1 Rapid Test Cassette	IDES-402
		HAV (Hepatitis A Virus) IgM Rapid Test Cassette	IHA-302
		HEV IgG/IgM Rapid Test Cassette	IHE-302
		H. pylori Antibody Rapid Test Cassette	IHP-402
		H. pylori Antigen (Helicobacter Pylori Antigen) Rapid Test Cassette	IHP-602
		H. pylori Antigen Rapid Test Dipstick	IHP-601
		H. pylori Antibody Rapid Test Dipstick	IHP-401
		H. pylori Antibody Rapid Test Cassette	IHP-302
		Influenza A+B Rapid Test Cassette	IIN-502
		Influenza A+B Rapid Test Dipstick	IIN-501
		Influenza A Rapid Test Cassette	IFLA-502
		Influenza A Rapid Test Dipstick	IFLA-501
		Leishmania IgG/IgM Rapid Test Cassette	ILEI-402
		Leptospira IgG/IgM Rapid Test Cassette	ILEP-402
		Malaria P. f. Rapid Test Dipstick	IMA-401
		Malaria P. f. Rapid Test Cassette	IMA-402
		MONO Rapid Test Cassette	MO-402
		Malaria P. f./Pan Rapid Test Cassette	IMPV-402
		Malaria P. f./P. v. Rapid Test Cassette	IMPV-402
		Norovirus Rapid Test Cassette	INO-602
		Rotavirus and Adenovirus Combo Rapid Test Cassette	IRAC-625
		Rotavirus Rapid Test Cassette	IRO-602
		Strep B Rapid Test Dipstick	ISB-501
		Strep B Rapid Test Cassette	ISB-502
		Strep A (Group A Streptococcus) Rapid Test Dipstick (Control in Red)	IST-501
		Strep A (Group A Streptococcus) Rapid Test Cassette (Control Line in Red)	IST-502
		Strep A (Group A Streptococcus) Rapid Test Dipstick (Control Line in Blue)	ISTB-501
		Strep A (Group A Streptococcus) Rapid Test Cassette (Control Line in Blue)	ISTB-502
		Syphilis Rapid Test Dipstick	ISY-401
		Syphilis Rapid Test Cassette	ISY-402
		Syphilis Rapid Test Dipstick	ISY-301
		Syphilis Rapid Test Cassette	ISY-302
		Tuberculosis (TB) Rapid Test Dipstick	ITB-401
		Tuberculosis (TB) Rapid Test Cassette	ITB-402
		Typhoid Rapid Test Cassette	ITY-402
		Typhoid Rapid Test Dipstick	ITY-401
		Typhoid Rapid Test Cassette	ITY-302
		Tetanus Rapid Test Cassette	ITE-402
		Gonorrhea Rapid Test Cassette	IGO-502
		HBsAg Rapid Test Cassette	IHB5G-302
		HBsAg Rapid Test Dipstick	IHB5G-301
		HBsAb Rapid Test Dipstick	IHB5B-401
		HBsAb Rapid Test Cassette	IHB5B-402
		HSV 1/2 IgG/IgM Rapid Test Cassette	ISGM-302
		HSV 1/2 IgG/IgM Combo Rapid Test Cassette	ISGM-325
		HSV 1/2 IgG/IgM Rapid Test Cassette	ISGM-402
		HSV 1/2 IgG/IgM Combo Rapid Test Cassette	ISGM-425
		Vaginal pH Rapid Test Panel	IVPH-504
		Brucella Abortus Antigen Rapid Test Cassette	IBA-402
		Clostridium difficile GDH Rapid Test Cassette	ICDG-602
		Filaria IgG/IgM Rapid Test Cassette	IFIL-302
		Filaria IgG/IgM Rapid Test Cassette	IFIL-402
		HAV IgG/IgM Combo Rapid Test Cassette	IHAGM-325
		Legionella Rapid Test Cassette	ILEG-102
		Mycoplasma Pneumoniae IgG/IgM Combo Rapid Test Cassette	IMP-425
		Mycoplasma pneumoniae Antigen Rapid Test Cassette	IMP-502
		Mycoplasma Pneumoniae IgM Rapid Test Cassette	IMPM-402
		RSV Rapid Test Cassette	IRS-502
		Salmonella Typhi Antigen Rapid Test Cassette	ISTY-602
		Zika NS1 Rapid Test Cassette	I2IG-402
		Giardia Lamblia Rapid Test Cassette	IGL-602
		Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test Cassette	ICD-635
		Clostridium difficile Toxin A + Toxin B Combo Rapid Test Cassette	ICD1-625
		Vitamin D Rapid Test Cassette	OVD-402
		Entamoeba histolytica Rapid Test Cassette	IEH-602
		Zika IgG/IgM Rapid Test Cassette	I2IB-402
		Zika IgG/IgM and NS1 Combo Rapid Test Cassette	I2IC-425
		RSV&Influenza A+B Combo Rapid Test Cassette	IRIC-525
		Adenovirus&RSV Combo Rapid Test Cassette	IARC-525
		Streptococcus pneumoniae Antigen Rapid Test Cassette	ISP-102
		Candida albicans Rapid Test	ICA-502
		Lyme IgG/IgM Rapid Test	ILY-402
		Vibrio cholerae O1 (VC O1) Rapid Test Cassette	IVCA-602
		Vibrio cholerae O139 (VC O139) Rapid Test Cassette	IVCB-602
		Vibrio cholerae O1/O139 Combo Rapid Test Cassette	IVCAB-625
		Malaria P. f./P. v. /Pan Rapid Test Cassette	IMPV-402
		Norovirus, Rotavirus and Adenovirus Combo Rapid Test Cassette	INRA-635
		Astrovirus Rapid Test Cassette	IAS-602
		Adenovirus, RSV and Influenza A+B Combo Rapid Test Cassette	IARI-535
		Campylobacter Rapid Test Cassette	ICAM-602
		Cryptosporidium Rapid Test Cassette	ICR-602
		Cryptosporidium and Giardia Lamblia Combo Rapid Test Cassette	ICCG-625
		ERV VCA IgG Rapid Test Cassette	IECG-402
		EBNA IgG Rapid Test Cassette	IENG-402
		EBV VCA and EBNA IgG Combo Rapid Test Cassette	IECNG-425
		Entamoeba/Giardia/Crypto Rapid Test Cassette (1 Window)	IEGC-602
		Entamoeba/Giardia/Crypto Combo Rapid Test Cassette (3 Windows)	IEGC-635
		Norovirus, Rotavirus, Adenovirus and Astrovirus Combo Rapid Test Cassette	IMVD-645
		Streptococcus pneumoniae and Legionella pneumophila Combo Rapid Test Cassette	ISLC-125
		Scrub Typhus IgG/IgM Rapid Test Cassette	ITSU-402

Influenza A+B Rapid Test Cassette (for Reader)	IIN-R502
H. pylori Antigen Rapid Test Cassette (for Reader)	IHP-R602
2019 nCoV (Novel Coronavirus) IgG/IgM Rapid Test Cassette	INCP-402S
2019 nCoV (Novel Coronavirus) IgG/IgM Rapid Test Cassette Single use kit	INCP-402B
COVID-19 (Novel Coronavirus) IgG/IgM Rapid Test Dipstick	INCP-411A
COVID-19 (Novel Coronavirus) IgG/IgM Rapid Test Dipstick	INCP-411B

8.2015

Hangzhou AllTest Biotech / MedNet GmbH
Sonstige Produkte / Other Devices

Registration Number DE	EDMA code	Product Name
DE/CA22/419-823-IVD	11-70-02-02-00 URINE MULTI- CONSTITUENT TEST STRIPS	Urinalysis Reagent Strips

06.07.2016

Liste B Produkte / List B devices

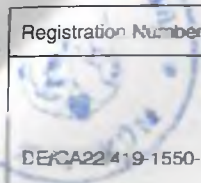
Registration Number DE	EDMA code	Product Name	Catalogue Number
DE,CA22/419-960-IVD	15-70-01-01-00 CHLAMYDIA AG - RAPID TEST	Chlamydia (CHL) Rapid Test Cassette	ICH-502

Sonstige Produkte / Other Devices

Registration Number DE	EDMA code	Product Name	Catalogue Number
DE/CA22/419-1137 1-IVD	12 70 05 90 00 OTHER FERTILITY / PREGNANCY RAPID TESTS	iGFBP-1 Rapid Test Cassette	FIG-502
		fn Rapid Test Cassette	FFF-502
		SP-10 Male Fertility Rapid Test Cassette (Semen)	OSP-902
		Sperm Concentration Rapid Test Cassette	OSC-902
		Fetal Fibronectin (fFN) Rapid Test Cassette (for Reader)	FFF-R502

Registration Number DE	Short Description	Product Name	Catalogue Number
DE/CA22 419-1317.2-ND	Rapid tests as an aid in the diagnosis of inflammatory conditions by detecting Serum Amyloid A (SAA) or/and C-reactive protein (CRP) or Lactoferrin or Procalcitonin (PCT) or Calprotectin in human specimen.	C-reactive protein Rapid Test Cassette	CCR-402
		C-reactive protein semi-quantitative Rapid Test Cassette	CCR-U402
		C-reactive protein Semi-Quantitative Rapid Test Cassette	CCR-T402
		CRP Rapid Test Dipstick	CCR-401
		CRP Semi-Quantitative Rapid Test Dipstick	CCR-U401
		SAA Rapid Test Cassette	OSA-402
		SAA and CRP Combo Rapid Test Cassette	OCSC-425
		Lactoferrin Rapid Test Cassette	OLF-602
		Procalcitonin (PCT) Rapid Test Cassette	CPC-302
		Procalcitonin (PCT) Rapid Test Cassette	CPC-402
		Procalcitonin (PCT) Rapid Test Cassette (for Reader)	CPC-R402
		Calprotectin Rapid Test cassette	OCAL-602
		Calprotectin Rapid Test Cassette (for Reader)	OCAL-R602
		C-Reactive Protein (CRP) Test Cassette (for Analyzer)	FI-CRP-402
		PCT Test Cassette (for Analyzer)	FI-PCT-402
		Calprotectin and Lactoferrin Combo Rapid Test Cassette	QIBD-625
Procalcitonin (PCT) Rapid Test Cassette (for Reader)	CPC-R302		

Sonstige Produkte / Other Devices

Registration Number DE	Short Description	Product Name	Catalogue Number
 <p>DECA22 419-1550-IVD</p>	<p>Urine Analyzer is a semi quantitative assessment of urine by using dry chemical methods. According to the principle of photoelectric colorimetry, urine analyzer is used to evaluate the content of biochemical components in the urine. It works with certain urinalysis reagents strips manufactured by Hangzhou Alltest Biotech CO., Ltd.</p>	Urine Analyzer	AUR-200
		Urine Analyzer	AUR-100
		Urine Analyzer	AUR-300

Die Echtheit der vorstehenden Unterschrift des
Regierungspharmaziedirektors der Bezirksregierung
Münster – Dr. Terhechte

und die Echtheit des Dienstsiegels werden hiermit
beglaubigt. Gleichzeitig wird bescheinigt, dass der
Vorgenannte zur Ausstellung dieser Urkunde berechtigt
war.



Münster, 28. Mai. 2020

Bezirksregierung Münster

Im Auftrag

Göcke

Göcke

Regierungsbeschäftigte



**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): **Göcke**

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

4. Và con dấu của/Dienstsiegel von: **Chính quyền hành chính vùng
Münster**

**được chứng nhận/hợp pháp hóa lãnh sự/
wird hiermit konsularisch beglaubigt/legalisiert**

5. Tại/in: **Berlin**

6. Ngày/Datum: **27/07/2020**

7. Cơ quan cấp/Ausgestellt von: **Đại sứ quán nước CHXHCN Việt Nam
tại CHLB Đức Botschaft der SR Vietnam in der BR Deutschland**
Số: **395-LS-HPH/2020**

8. Đại diện/A. des Botschafters
Tham Hoàng Tùng



Tham Hoàng Tùng