



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

Infection Disease Rapid Tests,
(for a detailed list please see attachment)
DIMDI Registration Numbers:
DE/CA22/419-822.3-IVD (other devices)
DE/CA22/419-1361-IVD (devices for self-testing)


on behalf of

Hangzhou AllTest Biotech Co., Ltd.
550 Yin Hai Street, Hangzhou Economic and Technological Development Area
310018 Hangzhou
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in Germany

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, 25.03.2020


MEDNET
Network to Market

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1 of 5

Product list as of 23.03.2020

DE/CA22/419-822.3-IVD (Other Devices)

Short Description	Product Name	Catalogue Number
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	IMO-402
	Malaria P.f./ Pan Rapid Test Cassette	IMPN-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 (Con-	ISTB-501	

2 of 5

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	Control Line in Blue)	
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
HSV 1/2 IgM Rapid Test Cassette		ISM-302
HSV 1/2 IgM Rapid Test Cassette		ISM-402
HSV 1/2 IgG Rapid Test Cassette		ISG-302
HSV 1/2 IgG Rapid Test Cassette		ISG-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
Filariasis IgG/IgM Rapid Test Cassette		IFIL-302
Filariasis 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		IZIG-402
Giardia Lambia 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		ICDT-625
Vitamin D Rapid Test Cassette		OVD-402
Entamoeba histolytica Rapid Test Cassette		IEH-602
Zika IgG/IgM Rapid Test Cassette		IZIB-402
Zika IgG/IgM and NS1 Combo Rapid Test Cassette		IZIC-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	IMPVF-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	ICGC-625
EBV 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-402
2019-nCoV (Novel Coronavirus) IgG/IgM Rapid Test Cassette Single use kit	INCP-402S
2019-nCoV (Novel Coronavirus) IgG/IgM Rapid Test Cassette	INCP-402B
COVID-19 (Novel Coronavirus) IgG/IgM Rapid Test Dipstick	INCP-411A
COVID-19 (Novel Coronavirus) IgG/IgM Rapid Test Dipstick	INCP-411B

Product list as of 06.08.2018

DE/CA22/419-1361-IVD (Devices for Self-Testing)

Short Description	Product Name	Catalogue Number
Rapid chromatographic immunoassays for determination of infection markers by investigating human specimen.	H. pylori Antigen Rapid Test Cassette	IHP-602H