



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

HCG (Human Chorionic Gonadotropin) Pregnancy Rapid Test
(for a detailed list please see attachment)

DIMDI Registration Numbers:

DE/CA22/419-818-IVD (other devices)

DE/CA22/419-820.1-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
P. R. China

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, 27.06.2019

Birthe Harms
MedNet GmbH



Network to Market

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Product list as of 24.07.2018

DE/CA22/419-818-IVD (Other Devices)

EDMA code	Product Name	Catalogue Number
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

Product list as of 17.05.2019

DE/CA22/419-820.1-IVD (Devices for Self-testing)

EDMA code	Product Name	Catalogue Number
12 70 05 02 00	Pregnancy (hCG) (Human Chorionic Gonadotropin) Rapid Test Midstream	FHC-103H
	Pregnancy (hCG) (Human Chorionic Gonadotropin) Enhanced Sensitivity Rapid Test Midstream	FHC-U103H
	Pregnancy (hCG) (Human Chorionic Gonadotropin) Rapid Test Cassette	FHC-102H
	Pregnancy (hCG) (Human Chorionic Gonadotropin) Rapid Test Dipstick	FHC-101H

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Pregnancy (hCG) Rapid Test Midstream With Indicator	FHC-103HI
Pregnancy (hCG) Enhanced Sensitivity Rapid Test Midstream With Indicator	FHC-U103HI
Pregnancy (hCG) (Human Chorionic Gonadotropin) Rapid Test Dipstick	FHC-F101H
Pregnancy (hCG) (Human Chorionic Gonadotropin) Rapid Test Cassette	FHC-F102H
Pregnancy (hCG) (Human Chorionic Gonadotropin) Rapid Test Midstream	FHC-F103H

