

Department for Regulation, Authorization,
Supervision of Medical Devices Market
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MINISTRY OF HEALTH
NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES
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**CERTIFICATE OF REGISTRATION
OF MEDICAL DEVICES
no. RO_IVD_208_449 of September 2nd 2015**

Pursuant to art. 932 par. (2) of Law no. 95/2006 on the healthcare reform, republished, to Order no. 372/2015 of the Minister of Health on the registration of medical devices, to art. 29 of the Government Decision no. 798/2003 on the establishment of conditions for placing on the market and using the in vitro diagnostic medical devices and based on the documentation submitted, the National Agency for Medicines and Medical Devices has registered in the database the medical devices listed below:

NAME OF THE DEVICE	TYPE	CODE	REGISTRATION CODE
hCG rapid test (human chorionic gonadotropin) – Trust Me	urine test – strip/cassette	TM 1.1/TM 1.2	RO_IVD_208_449_01
	urine/serum combo test - strip/cassette	TM 1.1`/TM 1.2`	
	urine test – pen/midstream	TM 1.2``	
LH rapid test (luteinizing hormone) – Trust Me	urine test – strip	TM 1.3	RO_IVD_208_449_02
	urine test – cassette	TM 1.4	
FSH rapid test (follicle-stimulating hormone) – Trust Me	urine test – strip	TM 1.5	RO_IVD_208_449_03
	urine test – cassette	TM 1.6	
Helicobacter Pylori rapid test – Trust Me	blood/serum/plasma test - cassette	TM 2.2	RO_IVD_208_440_04
	Stool antigen - cassette	TM 2.2'	
AFP rapid test (Alpha- fetoprotein)- Trust Me	serum/plasma test - strip	TM 3.1	RO_IVD_208_449_05
	serum/plasma test - cassette	TM 3.2	
CEA rapid test (carcinoembryonic antigen) – Trust Me	serum/plasma test - strip	TM 3.3	RO_IVD_208_449_06
	serum/plasma test - cassette	TM 3.4	
FAECAL OCCULT BLOOD rapid test (FOB)	stool test - cassette	TM 3.7	RO_IVD_208_449_07
Syphilis rapid test – Trust Me	serum/plasma test - strip	TM 4.1	RO_IVD_208_449_08
	blood/serum/plasma test - cassette	TM 4.2	
Gonorrhoea rapid test – Trust Me	swab test - cassette	TM 4.4	RO_IVD_208_449_09
TROPONIN I rapid test – Trust Me	blood/serum/plasma test - cassette	TM 6.1	RO_IVD_208_449_10
Myoglobin rapid test – Trust Me	blood/serum/plasma test - cassette	TM 6.2	RO_IVD_208_449_11



NAME OF THE DEVICE	TYPE	CODE	REGISTRATION CODE
CREATINE KINASE MB (CK-MB) rapid test – Trust Me	blood/serum/plasma test - cassette	TM 6.3	RO_IVD_208_449_12
AMPHETAMINE (AMP) rapid test – Trust Me	urine test – strip/cassette	TM 7.1	RO_IVD_208_449_13
BARBITURATES (BAR) rapid test – Trust Me	urine test – strip/cassette	TM 7.2	RO_IVD_208_449_14
BENZODIAZEPINES (BZO) rapid test – Trust Me	urine test – strip/cassette	TM 7.3	RO_IVD_208_449_15
COCAINE (COC) rapid test – Trust Me	urine test – strip/cassette	TM 7.4	RO_IVD_208_449_16
METHYLENEDIOXY-METHAMPHETAMINE (MDMA) rapid test – Trust Me	urine test – strip/cassette	TM 7.5	RO_IVD_208_449_17
METHAMPHETAMINE (MET) rapid test – Trust Me	urine test – strip/cassette	TM 7.6	RO_IVD_208_449_18
MORPHINE (MOP) rapid test – Trust Me	urine test – strip/cassette	TM 7.7	RO_IVD_208_449_19
METHADONE (MTD) rapid test – Trust Me	urine test – strip/cassette	TM 7.8	RO_IVD_208_449_20
OPIOID (OPI) rapid test – Trust Me	urine test – strip/cassette	TM 7.9	RO_IVD_208_449_21
TRICYCLIC ANTIDEPRESSANTS (TCA) rapid test – Trust Me	urine test – strip/cassette	TM 7.10	RO_IVD_208_449_22
MARIJUANA / CANNABIS (THC) rapid test – Trust Me	urine test – strip/cassette	TM 7.11	RO_IVD_208_449_23
PHENCYCLIDINE (PCP) rapid test – Trust Me	urine test – strip/cassette	TM 7.12	RO_IVD_208_449_24
BUPRENORPHINE (BUP) rapid test – Trust me	urine test – strip/cassette	TM 7.13	RO_IVD_208_449_25
OXYCODONUM (OXY) rapid test – Trust me	urine test – strip/cassette	TM 7.14	RO_IVD_208_449_26
PROPOXYPHENE (POX) rapid test – Trust me	urine test – strip/cassette	TM 7.15	RO_IVD_208_449_27
TRAMADOL (TRA) rapid test – Trust me	urine test – strip/cassette	TM 7.16	RO_IVD_208_449_28
K2 (Synthetic cannabis) rapid test – Trust me	urine test – strip/cassette	TM 7.17	RO_IVD_208_449_29
CARDIAC MARKERS 3 tests (cTnI, CK-MB, Myo) rapid test – Trust Me	panel - cassette	TM 6.X.3	RO_IVD_208_449_30
MALARIA PF, PF/PV (PLASODIUM FALCIPARUM) rapid test – Trust Me	whole blood test - cassette	TM 8.1 TM 8.1'	RO_IVD_208_449_31
DENGUE ANTIBODIES igG / IgM Ab rapid test – Trust Me	whole blood/serum/plasma test - cassette	TM 8.2	RO_IVD_208_449_32
DENGUE NS1 Ag. rapid test – Trust Me	serum/plasma test -cassette	TM 8.3	RO_IVD_208_449_33
TUBERCULOSIS rapid test – Trust Me	blood/serum/plasma test - cassette	TM 9.1	RO_IVD_208_449_34



placed on the market according to the provisions of Government Decision no. 798/2003 by the manufacturer:

SC CAMP MEDICA DISTRIBUTION SRL

headquartered in Bucharest, 29 Stanei st., district 4.

This registration has been carried out based on the manufacturer's or the authorized representative's statements and is not an approval or authorization from the competent authority.

By applying the EC marking, the manufacturer undertakes responsibility for the compliance of the product with all applicable requirements provided by Government Decision no. 798/2003.

The manufacturer must inform the National Agency for Medicines and Medical Devices on any amendment of the registered data, including cancellation of placement of devices on the market.

VICE PRESIDENT

Lazar IORDACHE

Illegible signature

Round seal

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