



**Department for Regulation, Authorization and Supervision of
Medical Devices Market**

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**HEALTH MINISTRY
NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES**

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**MEDICAL DEVICE REGISTRATION CERTIFICATE
NO. RO_IVD_208_466 OF February 3rd, 2016**

In accordance with Article 932, para. (2) of Law no. 95/2006 on healthcare reform, republished, Order of the Minister of Health no. 372/2015 on the registration of medical devices, Article 29 of Government Decision no. 798/2003 establishing the conditions for marketing and use of in vitro diagnostic medical devices and based on the documentation submitted, the National Agency for Medicines and Medical Devices has registered into its database the following medical devices:

DEVICE NAME	TYPE	CODE	REGISTRATION CODE
hCG (human chorionic gonadotropin) RAPID TEST – See Now	Urine test - strip/box	SN 1.1/SN 1.2	RO_IVD_208_466_01
	Combo urine/serum-strip/box	SN 1.1/SN 1.2'	
	Urine test – pen/midstream	SN 1.2''	
LH (luteinizing hormone) RAPID TEST – See Now	Urine test - strip	SN 1.3	RO_IVD_208_466_02
	Urine test - box	SN 1.4	
FSH (follicle stimulating hormone) RAPID TEST – See Now	Urine test - strip	SN 1.5	RO_IVD_208_466_03
	Urine test - box	SN 1.6	
HELICOBACTER PYLORI RAPID TEST – See Now	Whole blood/serum/plasma test -box	SN 2.2	RO_IVD_208_466_04
	Stool test - box	SN 2.2'	
AFP (alpha-fetoprotein) RAPID TEST – See Now	Serum/plasma test - strip	SN 3.1	RO_IVD_208_466_05
	Serum/plasma test - box	SN 3.2	
CEA (carcinogenic	Serum/plasma test -	SN 3.3	RO_IVD_208_466_06



embryonic antigen) RAPID TEST – See Now	strip		
	Serum/plasma test - box	SN 3.4	
Occult bleeding (FOB) RAPID TEST – See Now	Stool test - box	SN 3.7	RO_IVD_208_466_07
SYPHILIS RAPID TEST -See Now	Serum/plasma test - strip	SN 4.1	RO_IVD_208_466_08
	Serum/plasma test - box	SN 4.2	
GONORRHEA RAPID TEST – See Now	Secretion test - box	SN 4.4	RO_IVD_208_466_09
TROPONIN I RAPID TEST – See Now	Whole blood/serum/plasma test -box	SN 6.1	RO_IVD_208_466_10
MYOGLOBIN RAPID TEST – See Now	Whole blood/serum/plasma test -box	SN 6.2	RO_IVD_208_466_11
CREATINE KINASE (CK MS) RAPID TEST – See Now	Whole blood/serum/plasma test -box	SN 6.3	RO_IVD_208_466_12
CARDIAC MARKERS RAPID TEST – 3 tests (cTnl, CK-MB, Myo) - See Now	Panel -box	SN 6.X.3	RO_IVD_208_466_13
AMPHETAMINE (AMP) RAPID TEST - See Now	Urine test - strip/box	SN 7.1	RO_IVD_208_466_14
BARBITURATES (BAR) RAPID TEST - See Now	Urine test - strip/box	SN 7.2	RO_IVD_208_466_15
BENZODIAZEPINES (BZO) RAPID TEST See Now	Urine test - strip/box	SN 7.3	RO_IVD_208_466_16
COCAINE (COC) RAPID TEST – See Now	Urine test - strip/box	SN 7.4	RO_IVD_208_466_17
METHYLENEDIOXY- METHAMPHETAMINE (MDMA) RAPID TEST - See Now	Urine test - strip/box	SN 7.5	RO_IVD_208_466_18
METHAMPHETAMINE (MET) RAPID TEST - See Now	Urine test - strip/box	SN 7.6	RO_IVD_208_466_19
MORPHINE (MOP) RAPID TEST – See Now	Urine test - strip/box	SN 7.7	RO_IVD_208_466_20
METHADONE (MTD) RAPID TEST – See Now	Urine test - strip/box	SN 7.8	RO_IVD_208_466_21
OPIATES (OPI) RAPID TEST – See Now	Urine test - strip/box	SN 7.9	RO_IVD_208_466_22
TRICYCLIC	Urine test - strip/box	SN 7.10	RO_IVD_208_466_23



ANTIDEPRESSANTS (TCA) RAPID TEST - See Now			
MARIJUANA/CANNABIS (THC) RAPID TEST - See Now	Urine test - strip/box	SN 7.11	RO_IVD_208_466_24
PHENCYCLIDINE (PCP) RAPID TEST - See Now	Urine test - strip/box	SN 7.12	RO_IVD_208_466_25
BUPRENORPHINE (BUP) RAPID TEST - See Now	Urine test - strip/box	SN 7.13	RO_IVD_208_466_26
OXYCODONUM (OXY) RAPID TEST - See Now	Urine test - strip/box	SN 7.14	RO_IVD_208_466_27
PROPOXYPHENE (POX) RAPID TEST - See Now	Urine test - strip/box	SN 7.15	RO_IVD_208_466_28
METHAMPHETAMINE (MET) RAPID TEST - See Now	Urine test - strip/box	SN 7.6	RO_IVD_208_466_19
MORPHINE (MOP) RAPID TEST - See Now	Urine test - strip/box	SN 7.7	RO_IVD_208_466_20
METHADONE (MTD) RAPID TEST - See Now	Urine test - strip/box	SN 7.8	RO_IVD_208_466_21
OPIATES (OPI) RAPID TEST - See Now	Urine test - strip/box	SN 7.9	RO_IVD_208_466_22
TRICYCLIC ANTIDEPRESSANTS (TCA) RAPID TEST - See Now	Urine test - strip/box	SN 7.10	RO_IVD_208_466_23
MARIJUANA/CANNABIS (THC) RAPID TEST - See Now	Urine test - strip/box	SN 7.11	RO_IVD_208_466_24
PHENCYCLIDINE (PCP) RAPID TEST - See Now	Urine test - strip/box	SN 7.12	RO_IVD_208_466_25
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PROPOXYPHENE (POX) RAPID TEST - See Now	Urine test - strip/box	SN 7.15	RO_IVD_208_466_28
TRAMADOL (TRA) RAPID TEST - See Now	Urine test - strip/box	SN 7.16	RO_IVD_208_466_29
K2 (Synthetic Cannabis) RAPID TEST - See Now	Urine test - strip/box	SN 7.17	RO_IVD_208_466_30
MALARIA, PF, PF/PV (PLASODIUM)	Whole blood test - box	SN 8.1 SN 8.1'	RO_IVD_208_466_31



FALCIPARUM) RAPID TEST -See Now			
DENGUE IgG/IgM Ab RAPID TEST - See Now	Whole blood/serum/plasma - box	SN 8.2	RO_IVD_208_466_32
DENGUE NS1 Ag RAPID TEST - See Now	Serum/plasma test - box	SN 8.3	RO_IVD_208_466_33
TUBERCULOSIS RAPID TEST - See Now	Blood/serum/plasma test	SN 9.1	RO_IVD_208_466_34

placed on the market in accordance with the Government Decision no. 798/2003 by the manufacturer:

SC CAMP MEDICA DISTRIBUTION SRL

with registered office in Bucharest, 29 Stanei Street, sector 4.

This registration was performed based on the statements made by the manufacturer or its authorized representative and is not an approval or authorization from the competent authority.

By affixing the CE marking, the manufacturer assumes responsibility for the product compliance with all applicable requirements specified by Government Decision no. 798/2003.

The manufacturer shall communicate to the National Agency for Medicines and Medical Devices any change in the recorded data, including suspension of the placing of these devices on the market.

**VICEPRESIDENT,
Engineer Lazar IORDACHE**

*Illegible signature
Round stamp*

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