

Department for Regulation, Authorization and Supervision of
Medical Devices Market

58 Nicolae Titulescu Blvd., sector 1

Tel: +40-21.222.86.52 / 260.01.59

Fax: +40-21.222.86.83

HEALTH MINISTRY
NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES

48 Av. Sanatescu Street, Bucharest

011478, sector 1

Tel: + 40-21.317.11.02 / 317.11.15

Fax: + 40-21.316.34.97 / 031.805.74.54

ANNEX 1/February 9th, 2016
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:

DENUMIRE DISPOZITIV	TIP	COD	COD INREGISTRARE
URINE DRUG TESTING - SeeNow	Panel 2 DOA (AMP, THC)	SN 7.X.2.1	RO_IVD 208 466 35
URINE DRUG TESTING - See Now	Panel 2 DOA (COC, THC)	SN 7.X.2.2	RO IVD_208_466_36
URINE DRUG TESTING - See Now	Panel 2 DOA (MET, THC)	SN 7.X.2.3	ROJVD 208_466_37
URINE DRUG TESTING - See Now	Panel 3 DOA (AMP, MET, MOP)	SN 7.X.3.1	ROJVD_208_466_38
URINE DRUG TESTING - See Now	Panel 3 DOA (AMP, BAR, BZO)	SN 7.X.3.2	RO_IVD_208 466_39
URINE DRUG TESTING - See Now	Panel 3 DOA (AMP, COC,THC)	SN 7.X.3.3	RO_IVD_208_466_40
URINE DRUG TESTING - See Now	Panel 3 DOA (BAR, BZO, BUP)	SN 7.X.3.4	RO_IVD_208_466_41
URINE DRUG TESTING - See Now	Panel 3 DOA (BZO, MDMA, MTD)	SN 7.X.3.5	ROJVD_208_466_42
URINE DRUG TESTING - See Now	Panel 4 DOA (AMP, COC, THC, PCP)	SN 7.X.4.1	RO_JVD,208_466 43
URINE DRUG TESTING - See Now	Panel 4 DOA (AMP, BAR, COC,PCP)	SN 7.X.4.2	RO IVD 208 466 44
URINE DRUG TESTING - See Now	Panel 4 DOA (AMP, COC, OPI.TRA)	SN 7.X.4.3	ROJVD,208_466_45
URINE DRUG TESTING-See Now	Panel 4 DOA (AMP, MDMA, OPI, THC)	SN 7.X.4.4	ROJVD_208 466 46



DENUMIRE DISPOZITIV	TIP	COD	COD INREGISTRARE
URINE DRUG TESTING - See Now	Panel 4 DOA (AMP, MET, MOP, THC)	SN 7.X.4.5	ROJVD_208_466_47
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BAR, BZO, CO THC)	SN 7.X.5.1	RO_IVD_208_466_48
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, COC, MDM, OPI, THC)	SN 7.X.5.2	RO_IVD_208_466_49
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BAR, COC, MET, THC)	SN 7.X.5.3	RO_IVD_208_466_50
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BZO, COC, OPI, THC)	SN 7.X.5.4	ROJVD_208_466_51
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BAR, BZO, COC, OPI)	SN 7.X.5.5	RO_IVD_208_466_52
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, COC, MET, OPI, THC)	SN 7.X.5.6	RO_IVD_208_466_53
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BAR, BZO, BUP, COC)	SN 7.X.5.7	ROJVD_208_466_54
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BAR, BZO, BUP, THC)	SN 7.X.5.3	RO_IVD_208_466_55
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BAR, COC, THC, PCP)	SN 7.X.5.9	RO_IVD_208_466_56
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BAR, COC, MET, PCP)	SN 7.X.5.10	RO_IVD_208_466_57
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BAR, COC, OPI, PCP)	SN 7.X.5.11	RO_IVD_208_466_58
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BAR, BZO, OPI, PCP)	SN 7.X.5.12	ROJVD_208_466_59
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BAR, MDMA, THC, PCP)	SN 7.X.5.13	RO_IVD_208_466_60
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BAR, COC, MDMA, PCP)	SN 7.X.5.14	RO_IVD_208_466_61
URINE DRUG TESTING - See Now	Panel 5 DOA (AMP, BAR, BZO, THC, PCP)	SN 7.X.5.15	ROJVD_208_466_62
URINE DRUG TESTING - See Now	Panel 6 DOA (BUP, BZD, MET, OPI, THC, CRE)	SN 7.X.6.1	RO_IVD_208_466_63
URINE DRUG TESTING - See Now	Panel 6 DOA (AMP, BZO, BUP, COC, OPI, THC)	SN 7.X.6.2	ROJVD_208_466_64
URINE DRUG TESTING - See Now	Panel 6 DOA (AMP, BAR, BZO, COC, OPI, CRE)	SN 7.X.6.3	ROJVD_208_466_65
URINE DRUG TESTING - See Now	Panel 6 DOA (BZO, COC, MET, OPI, PCP, THC)	SN 7.X.6.4	RO_IVD_208_466_66



DENUMIRE DISPOZITIV	TIP	COD	COD INREGISTRARE
URINE DRUG TESTING - See Now	Panel 6 DOA (BAR, BZO, BUP, COC, THC, pH)	SN 7.X.6.5	ROJVD_208_466_67
URINE DRUG TESTING * See Now	Panel 7 DOA (AMP, COC, MDMA, MET, MOP, MTD, THC)	SN 7.X.7	RO_IVD_208_466_68
URINE DRUG TESTING - See Now	Panel 8 DOA (AMP, BUP, COC, MDMA, MET, MOP, MTD, THC)	SN 7.X.8.1	RO_IVD_208_466_69
URINE DRUG TESTING - See Now	Panel 8 DOA (AMP, COC, MDMA, MET, MOP, MTD, THC, CRE)	SN 7.X.8.2	ROJVD_208_466_70
URINE DRUG TESTING - See Now	Panel 8 DOA (AMP, COC, MDMA, MET, MOP, MTD, THC, pH)	SN 7.X.8.3	RO_IVD_208_466_71
URINE DRUG TESTING - See Now	Panel 9 DOA (AMP, BUP, COC, MDMA, MET, MOP, MTD, THC, CRE)	SN 7.X.9.1	RO_IVD_208_466_72
URINE DRUG TESTING - See Now	Panel 9 DOA (AMP, BUP, COC, MDMA, MET, MOP, MTD, THC, pH)	SN 7.X.9.2	RO_IVD_208_466_73
URINE DRUG TESTING - See Now	Panel 10(DOA (AMP, BUP, COC, MDMA, MET, MOP, MTD, THC, CRE, pH)	SN 7.X.10.1	ROJVD_208_466_74
URINE DRUG TESTING - See Now	Panel 10 DOA (AMP, BAR, BZO, BUP, COC, MDMA, MET, MTD, OPI, TCA, THC)	SN 7.X.10.2	ROJVD_208_466_75
URINE DRUG TESTING - See Now	Panel 10 DOA (AMP, BAR, BZO, COC, MDMA, MET, MTD, OPI, TCA, THC)	SN 7.X.10.3	RO_IVD_208_466_76
URINE DRUG TESTING - See Now	Panel 10 DOA (AMP, BAR, BZO, COC, MDMA, MET, MTD, OPI, THC, TRA)	SN 7.X.10.4	RO_IVD_208_466_77
URINE DRUG TESTING - See Now	Panel 10 DOA (AMP, BAR, BZO, COC, MDMA, MTD, OPI, TCA, THC, POX)	SN 7.X.10.5	RO_IVD_208_466_78
URINE DRUG TESTING - See Now	Panel 10 DOA (AMP, BAR, COC, MET, MTD, OPI, TCA, THC, PCP, TRA)	SN 7.X.10.6	ROJVD_208_466_79
URINE DRUG TESTING - See Now	Panel 10 DOA (AMP, BAR, BUP, COC, MET, MTD, OPI, TCA, THC, PCP)	SN 7.X.10.7	RO_IVD_208_466_80
URINE DRUG TESTING - See Now	Panel 10 DOA (AMP, BAR, BZO, COC, MDMA, MET, MTD, OPI, THC, PCP)	SN 7.X.10.8	RO_IVD_208_466_81
URINE DRUG TESTING-See Now	Panel 10 DOA (AMP, BAR, BZO, COC, MDMA, MTD, OPI, TRA, THC, OXY)	SN 7.X.10.9	RO_IVD_208_466_82
URINE DRUG TESTING - See Now	Panel 10 DOA (AMP, BAR, BZO, BUP, COC, MTD, OPI, TCA, THC, PCP)	SN 7.X.10.10	RO_IVD_208_466_83
URINE DRUG TESTING - See Now	Panel 10 DOA (AMP, BAR, BZO, BUP, COC, MDMA, MTD, OPI, THC, PCP,)	SN 7.X.10.11	RO_IVD_208_466_84



DENUMIRE DISPOZITIV	TIP	COD	COD ÎNREGISTRARE
URINE DRUG TESTING - See Now	Panel 12 DOA (AMP, BAR, BZO, BUP, COC, MDMA, MET, MTD, OPI, TCA, THC, PCP)	SN 7.X.12.1	RO_IVD_208_466_85
URINE DRUG TESTING - See Now	Panel 12 DOA (AMP, BAR, BZO, BUP, COC, MDMA, MET, MTD, OPI, TCA, THC, OXY)	SN 7.X.12.2	RO_IVD_208_466_86
URINE DRUG TESTING - See Now	Panel 12 DOA (AMP, BAR, BZO, BUP, COC, MDMA, MET, MTD, OPI, TCA, THC, POX)	SN 7.X.12.3	RO_IVD_208_466_87
URINE DRUG TESTING - See Now	Panel 12 DOA (AMP, BAR, BZO, BUP, COC, MDMA, MET, MTD, OPI, TCA, THC, TRA)	SN 7.X.12.4	RO_IVD_208_466_88
URINE DRUG TESTING - See Now	Panel 12 DOA (AMP, BAR, BZO, COC, MET, MTD, OPI, OXV, PCP, POX, THC, TRA)	SN 7.X.12.5	RO_IVD_208_466_89

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

I, **GRECU SIMONA OANA**, an authorized translator and interpreter for the languages English and German, based on authorization no. 12906 from 01.06.2005, issued by the Romanian Ministry of Justice, certify the accuracy of this translation from **Romanian into English**, the fact that source text was translated in full, without omissions and that the content and the meaning of the source document were not altered through the translation. The source document to be translated in full has a total of 4 pages; it is entitled **ANNEX 1**, was issued by the **HEALTH MINISTRY**, and was presented to me in full. The translation of the document has 4 pages and it was done based on the written application no. GTGSO757/22.12.2016, kept in my records. The fee amounting to lei 78 were paid with PO/22.12.2016.

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NICA SANDA
notar public

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