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Supervision of Medical Devices Market
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MINISTRY OF HEALTH
NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES
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**ANNEX no. 2 / October 6th 2015 to the
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
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 2 DOA (AMP, THC)	TM 7.X.2.1	RO_IVD_208_449_37
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 2 DOA (COC, THC)	TM 7.X.2.2	RO_IVD_449_208_38
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 2 DOA (MET, THC)	TM 7.X.2.3	RO_IVD_208_449_39
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 3 DOA (AMP, MET, MOP)	TM 7.X.3.1	RO_IVD_208_449_40
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 3 DOA (AMP, BAR, BZO)	TM 7.X.3.2	RO_IVD_208_449_41
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 3 DOA (AMP, COC, THC)	TM 7.X.3.3	RO_IVD_208_449_42



RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 3 DOA (BAR, BZO, BUP)	TM 7.X.3.4	RO_IVD_208_449_43
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 3 DOA (BZO, MDMA, MTD)	TM 7.X.3.5	RO_IVD_208_449_44
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 4 DOA (AMP, COC, THC, PCP)	TM 7.X.4.1	RO_IVD_208_449_45
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 4 DOA (AMP, BAR, COC, PCP)	TM 7.X.4.2	RO_IVD_208_449_46
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 4 DOA (AMP, COC, OPI, TRA)	TM 7.X.4.3	RO_IVD_208_449_47
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 4 DOA (AMP, MDMA, OPI, THC)	TM 7.X.4.4	RO_IVD_208_449_48
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 4 DOA (AMP, MET, MOP, THC)	TM 7.X.4.5	RO_IVD_208_449_49
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BAR, BZO, COC, THC)	TM 7.X.5.1	RO_IVD_208_449_50
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, COC, MDMA, OPI, THC)	TM 7.X.5.2	RO_IVD_208_449_51
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BAR, COC, MET, THC)	TM 7.X.5.3	RO_IVD_208_449_52
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BZO, COC, OPI, THC)	TM 7.X.5.4	RO_IVD_208_449_53
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BAR, BZO, COC, OPI)	TM 7.X.5.5	RO_IVD_208_449_54



Trust Me			
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, COC, MET, OPI, THC)	TM 7.X.5.6	RO_IVD_208_449_55
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BAR, BZO, BUP, COC)	TM 7.X.5.7	RO_IVD_208_449_56
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BAR, BZO, BUP, THC)	TM 7.X.5.8	RO_IVD_208_449_57
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BAR, COC, THC, PCP)	TM 7.X.5.9	RO_IVD_208_449_58
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BAR, COC, MET, PCP)	TM 7.X.5.10	RO_IVD_208_449_59
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BAR, COC, OPI, PCP)	TM 7.X.5.11	RO_IVD_208_449_60
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BAR, BZO, OPI, PCP)	TM 7.X.5.12	RO_IVD_208_449_61
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BAR, MDMA, THC, PCP)	TM 7.X.5.13	RO_IVD_208_449_62
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BAR, COC, MDMA, PCP)	TM 7.X.5.14	RO_IVD_208_449_63
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 5 DOA (AMP, BAR, BZO, THC, PCP)	TM 7.X.5.15	RQ_IVD_208_44S_64
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 6 DOA (BUP, BZD, MET, OPI, THC, CRE)	TM 7.X.6.1	RO_IVD_208_449_65
RAPID URINE TEST FOR	Panel 6 DOA (AMP, BZO, BUP, COC, OPI, THC)	TM 7.X.6.2	RO_IVD_208_449_66



DRUG DETECTION - Trust Me			
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 6 DOA (AMP, BAR, BZO, COC, OPI, CRE)	TM 7.X.6.3	RO_IVD_208_449_67
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 6 DOA (BZO, COC, MET, OPI, PCP, THC)	TM 7.X.6.4	RO_IVD_208_449_68
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 6 DOA (BAR, BZO, BUP, COC, THC, pH)	TM 7.X.6.5	RO_IVD_203_449_69
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 7 DOA (AMP, COC, MDMA, MET, MOP, MTD, THC)	TM 7.X.7	RO_IVD_208_449_70
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 8 DOA (AMP, BUP, COC, MDMA, MET, MOP, MTD, THC)	TM 7.X.8.1	RO_IVD_208_449_71
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 8 DOA (AMP, COC, MDMA, MET, MOP, MTD, THC, CRE)	TM 7.X.8.2	RO_IVD_208_449_72
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 8 DOA (AMP, COC, MDMA, MET, MOP, MTD, THC, pH)	TM 7.X.8.3	RO_IVD_208_449_73
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 9 DOA (AMP, BUP, COC, MDMA, MET, MOP, MTD, THC, CRE)	TM 7.X.9.1	RO_IVD_208_449_
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 9 DOA (AMP, BUP, COC, MDMA, MET, MOP, MTD, THC, pH)	TM 7.X.9.2	RO_IVD_208_449_75
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 10 DOA (AMP, BUP, COC, MDMA, MET, MOP, MTD, THC, CRE, pH)	TM 7.X.10.1	RO_IVD_208_449_76
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 10 DOA (AMP, BAR, BZO, BUP, COC, MDMA, MET, MTD, OPI, THC)	TM 7.X.10.2	RO_IVD_208_449_77

RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 10 DOA (AMP, BAR, BZO, COC, MDMA, MET, MTD, OPI, TCA, THC)	TM 7.X.10.3	RO_IVD_208_449_78
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 10 DOA (AMP, BAR, BZO, COC, MDMA, MET, MTD, OPI, THC, TRA)	TM 7.X.10.4	RO_IVD_208_449_79
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 10 DOA (AMP, BAR, BZO, COC, MDMA, MTD, OPI, TCA, THC, POX)	TM 7.X.10.5	RO_IVD_208_449_80
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 10 DOA (AMP, BAR, COC, MET, MTD, OPI, TCA, THC, PCP, TRA)	TM 7.X.10.6	RO_IVD_208_449_81
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 10 DOA (AMP, BAR, BUP, COC, MET, MTD, OPI, TCA, THC, PCP)	TM 7.X.10.7	RO_IVD_208_449_82
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 10 DOA (AMP, BAR, BZO, COC, MDMA, MET, MTD, OPI, THC, PCP)	TM 7.X.10.8	RO_IVD_208_449_83
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 10 DOA (AMP, BAR, BZO, COC, MDMA, MTD, OPI, TRA, THC, OXY)	TM 7.X.10.9	RO_IVD_208_449_84
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 10 DOA (AMP, BAR, BZO, BUP, COC, MTD, OPI, TCA, THC, PCP)	TM 7.X.10.10	RO_IVD_208_449_85
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 10 DOA (AMP, BAR, BZO, BUP, COC, MDMA, MTD, OPI, THC, PCP)	TM.X.10.11	RO_IVD_208_449_86
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 12 DOA (AMP, BAR, BZO, BUP, COC, MDMA, MET, MTD, OPI, TCA, THC, PCP)	TM 7.X.12.1	RO_IVD_208_449_87
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 12 DOA (AMP, BAR, BZO, BUP, COC, MDMA, MET, MTD, OPI, TCA, THC, OXY)	TM 7.X.12.2	RO_IVD_208_449_88
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 12 DOA (AMP, BAR, BZO, BUP, COC, MDMA, MET, MTD, OPI, TCA, THC, POX)	TM 7.X.12.3	RO_IVD_208_449_89



Trust Me			
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 12 DOA (AMP, BAR, BZO, BUP, COC, MDMA, MET, MTD, OPI, TCA, THC, TRA)	TM 7.X.12.4	RO_IVD_208_449_90
RAPID URINE TEST FOR DRUG DETECTION - Trust Me	Panel 12 DOA (AMP, BAR, BZO, COC, MET, MTD, OPI, OXY, PCP, POX, THC, TRA)	TM 7.X.12.5	RO_IVD_208_449_91

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

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 3 pages, it is entitled ANNEX TO CERTIFICATE OF REGISTRATION OF MEDICAL DEVICES, was issued by MINISTRY OF HEALTH, and was presented to me in full. The translation of the document has 6 pages and it was done based on the written application no. GTGSO33/21.01.2016, kept in my records. The fee amounting to lei 70.2 was paid, with PO/21.01.2016.

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Rădulescu Veronica
notar public

No./Nr. 125 of/din 21.01.2016

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Rădulescu Verónica
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