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## DECLARATION OF CONFORMITY

According to essential requirements of the Directive 98/79/EC for in vitro diagnostic medical devices, of the European Council, the

◆ **Manufacturer** **Camp Medica Distribution SRL**  
No. 29 Stanei Street, Sector 4, Bucharest – Romania

declare under our sole responsibility that the following IVD medical devices,

◆ **Product name** **See Now** in vitro diagnostic rapid tests – see Annex I,

meet the provisions of the European Directive 98/79/EC, concerning in vitro diagnostic medical devices, which apply to them.

◆ **Requests** European Directive no. 98/79/CE from October 27th, of the European Parliament Council for in vitro diagnostic medical devices

◆ **Classification** medical devices for in vitro diagnostic (IVDD)  
EDMA Code : see annex I

The following standards were used to prove the products conformity with the essential requirements of the above directive: **SR EN ISO 13485:2016**.

◆ **Standards Applied** EN 375: 2001, EN 980: 2008, EN 13612: 2002, EN 13640:2002,  
EN 13641:2002, SR EN ISO 14971:2012, SR EN ISO 13485:2016

◆ **Place, Date of Issue** Bucharest – Romania, 25.02.2020

**Quality Manager**  
Dr. Eng. Carolina Constantin

## Annex I

CODE	Product name	Format	EDMS code
SN 1.1/ SN 1.2	<b>See Now</b> hCG (Chorionic Gonadotropin)	strip/cassette	12 70 05 02 00
SN 1.3/ SN 1.4	<b>See Now</b> LH (leuteinizing hormone)	strip/cassette	12 70 05 04 00
SN 1.5/ SN 1.6	<b>See Now</b> FSH (follicle stimulating hormone)	strip/cassette	12 70 05 01 00
SN 2.2/ SN 2.2'	<b>See Now</b> H. Pylori (antibody / antigen)	strip/cassette	15 70 01 02 00
SN 2.3	<b>See Now</b> HIV	cassette	15 70 03 02 00
SN 3.1/ SN 3.2	<b>See Now</b> AFP-Alpha Fetoprotein	strip/cassette	12 70 03 90 00
SN 3.3/ SN 3.4	<b>See Now</b> CEA-Carcinoma Embryonic Antigen	strip/cassette	12 70 03 90 00
SN 3.5/SN 3.6	<b>See Now</b> PSA (Prostatic Specific Antigen)	strip/cassette	12 70 03 11 10
SN 3.7	<b>See Now</b> FOB (Fecal Occult Blood)	cassette	11 70 03 01 00
SN 4.1/ SN 4.2	<b>See Now</b> Syphilis	strip/cassette	15 70 01 05 00
SN 4.3/ SN 4.4	<b>See Now</b> Gonorrhoea	strip/cassette	15 70 01 90 00
SN 4.5	<b>See Now</b> Chlamydia Ag.	Cassette	15 70 01 01 00
SN 5.1/SN 5.2	<b>See Now</b> HBsAg	strip/cassette	15 70 02 01 00
SN 5.3/SN 5.4	<b>See Now</b> HCV Ab	strip/cassette	15 70 02 02 00
SN 5.5/ SN 5.6	<b>See Now</b> Anti-HBs	strip/cassette	15 70 02 90 00
SN 5.7/ SN 5.8	<b>See Now</b> Anti-HBc	strip/cassette	15 70 02 90 00
SN 5.9/ SN 5.10	<b>See Now</b> Anti-HBe	strip/cassette	15 70 02 90 00
SN 5.11/ SN 5.12	<b>See Now</b> HBeAg	strip/cassette	15 70 02 90 00
SN 5.13	<b>See Now</b> Anti- HAV IgG/IgM	cassette	15 02 01 05/06 00
SN 5.14	<b>See Now</b> Anti- HEV IgG/IgM	cassette	15 02 05 05/06 00
SN 5.14'	<b>See Now</b> Anti- HEV IgM	cassette	15 02 05 06 00
SN 6.1	<b>See Now</b> Troponin I	cassette	12 70 13 03 00
SN 6.2	<b>See Now</b> Myoglobin	cassette	12 70 13 02 00
SN 6.3	<b>See Now</b> CK-MB	cassette	12 70 13 01 00
SN 6.X.3	<b>See Now</b> Cardiac panel (cTnl,CK-MB, Myo)	panel	12 70 13
SN 7.1/SN 7.1'	<b>See Now</b> Amphetamine (AMP)	cassette/ strip	12 70 09 01 00
SN 7.2/ SN 7.2'	<b>See Now</b> Barbiturate (BAR)	cassette/ strip	12 70 09 03 00
SN 7.3/ SN 7.3'	<b>See Now</b> Benzodiazepine (BZD)	cassette/ strip	12 70 09 04 00
SN 7.4/ SN 7.4'	<b>See Now</b> Cocaine (COC)	cassette/ strip	12 70 09 06 00
SN 7.5/ SN 7.5'	<b>See Now</b> Methylenedioxymeth-amphetamine(MDMA)	cassette/ strip	12 70 09 90 00
SN 7.6/ SN 7.6'	<b>See Now</b> Methamphetamine (MET)	cassette/ strip	12 70 09 90 00
SN 7.7/ SN 7.7'	<b>See Now</b> Morphine (MOP)	cassette/ strip	12 70 09 08 00
SN 7.8/ SN 7.8'	<b>See Now</b> Methadone (MTD)	cassette/ strip	12 70 09 07 00
SN 7.9/ SN 7.9'	<b>See Now</b> Opiate (OPI)	cassette/ strip	12 70 09 08 00
SN 7.10/ SN 7.10'	<b>See Now</b> Tricyclic Antidepressants (TCA)	cassette/ strip	12 70 09 10 00
SN 7.11/ SN 7.11'	<b>See Now</b> Marijuana (THC)	cassette/ strip	12 70 09 05 00
SN 7.12/ SN 7.12'	<b>See Now</b> Phencyclidine (PCP)	cassette/ strip	12 70 09 09 00
SN 7.13/ SN 7.13'	<b>See Now</b> Buprenorphine (BUP)	cassette/ strip	12 70 09 90 00
SN 7.14/ SN 7.14'	<b>See Now</b> Oxycodone (OXY)	cassette/ strip	12 70 09 90 00
SN 7.15/ SN 7.15'	<b>See Now</b> Propoxyphene (POX)	cassette/ strip	12 70 09 90 00
SN 7.16/ SN 7.16'	<b>See Now</b> Tramadol (TRA)	cassette/ strip	12 70 09 90 00
SN 7.17/ SN 7.17'	<b>See Now</b> Marijuana synthetic (K2)	cassette/ strip	12 70 09 90 00
SN 7.X.2 – 7.X.12	<b>See Now</b> DOA panels (2 – 12 DOA tests)	panel	12 70 09
SN 8.1	<b>See Now</b> Malaria pf/pv	cassette	14 05 02 02 00
SN 8.2	<b>See Now</b> Dengue virus IgG/IgM Ab.	cassette	15 04 80 11 00
SN 8.3	<b>See Now</b> Dengue virus NS1 Ag.	cassette	15 04 80 11 00
SN 8.4	<b>See Now</b> Dengue Combo IgG/IgM+NS1	panel	15 04 80 11 00
SN 8.5	<b>See Now</b> Coronavirus 2019 nCoV Ab.	cassette	15 70 90 90 00
SN 8.6	<b>See Now</b> Influenza A+B Ag.	cassette	15 70 90 04 00
SN 9.1	<b>See Now</b> Tuberculosis	cassette	15 01 07 03 00
SN 9.2	<b>See Now</b> Salmonella IgG/IgM	cassette	15 01 10 03 00
SN 10.1	<b>See Now</b> Rubella IgG/IgM	cassette	15 04 01 04 00
SN 10.2	<b>See Now</b> Toxoplasma IgG/IgM	cassette	15 05 01 04 00
SN 10.3	<b>See Now</b> CMV IgG/IgM	cassette	15 04 02 04 00
TM 11.1	<b>Trust Me</b> Tetanus Ab.	cassette	15 01 40 09 00
SN 12.1	<b>See Now</b> Alcohol	cassette	12 09 02 07 00
SN 13.1/2/3/4	<b>See Now</b> Urine strips 10/11/12/13 parameters	strip	11 70 02 02 00
SN 13.X.3	<b>See Now</b> Urinary Tract Infection (UTI) test	strip	11 70 02 02 00

**Quality Manager**

Dr. Eng. Carolina Constantin