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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 device,

◆ **Product name** **See Now** in vitro diagnostic rapid tests – see Annex 1,

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 13485:2012.**

◆ **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 13485:2012

◆ **Place, Date of Issue** Bucharest – Romania, 01.11.2016

Quality Manager

Dr. Eng. Carolina Constantin

Annex I

CODE	Product name	EDMS code
SN 1.1/ SN 1.2	See Now hCG (Chorionic Gonadotropin)	12 70 05 02 00
SN 1.3/ SN 1.4	See Now LH (leuteinizing hormone)	12 70 05 04 00
SN 1.5/ SN 1.6	See Now FSH (follicle stimulating hormone)	12 70 05 01 00
SN 2.2/ SN 2.2'	See Now H. Pylori (antibody / antigen)	15 70 01 02 00
SN 3.1/ SN 3.2	See Now AFP-Alpha Fetoprotein	12 70 03 90 00
SN 3.3/ SN 3.4	See Now CEA-Carcinoma Embryonic Antigen	12 70 03 90 00
SN 3.5/SN 3.6	See Now PSA (Prostatic Specific Antigen)	12 70 03 11 10
SN 3.7	See Now FOB (Fecal Occult Blood)	11 70 03 01 00
SN 4.1/ SN 4.2	See Now Syphilis	15 70 01 05 00
SN 4.3/ SN 4.4	See Now Gonorrhoea	15 70 01 90 00
SN 5.1/SN 5.2	See Now HBsAg	15 70 02 01 00
SN 5.3/SN 5.4	See Now HCVAb	15 70 02 02 00
SN 5.5/ SN 5.6	See Now Anti-HBs	15 70 02 90 00
SN 5.7/ SN 5.8	See Now Anti-HBc	15 70 02 90 00
SN 5.9	See Now Anti- HAV	12 70 02 90 00
SN 6.1	See Now Troponin I	12 70 13 03 00
SN 6.2	See Now Myoglobin	12 70 13 02 00
SN 6.3	See Now CK-MB	12 70 13 01 00
N 7.1	See Now Amphetamine (AMP)	12 70 09 01 00
SN 7.2	See Now Barbiturate (BAR)	12 70 09 03 00
SN 7.3	See Now Benzodiazepine (BZD)	12 70 09 04 00
SN 7.4	See Now Cocaine (COC)	12 70 09 06 00
SN 7.5	See Now Methylendioxy-meth-amphetamine(MDMA)	12 70 09 90 00
SN 7.6	See Now Methamphetamine (MET)	12 70 09 90 00
SN 7.7	See Now Morphine (MOP)	12 70 09 08 00
SN 7.8	See Now Methadone (MTD)	12 70 09 07 00
SN 7.9	See Now Opiate (OPI)	12 70 09 08 00
SN 7.10	See Now Tricyclic Antidepressants (TCA)	12 70 09 10 00
SN 7.11	See Now Marijuana (THC)	12 70 09 05 00
SN 7.12	See Now Phencyclidine (PCP)	12 70 09 09 00
SN 7.13	See Now Buprenorphine (BUP)	12 70 09 90 00
SN 7.14	See Now Oxycodone (OXY)	12 70 09 90 00
SN 7.15	See Now Propoxyphene (POX)	12 70 09 90 00
SN 7.16	See Now Tramadol (TRA)	12 70 09 90 00
SN 7.17	See Now Marijuana synthetic (K2)	12 70 09 90 00
SN 7.X.2 – SN 7.X.12	See Now DOA panels (2 – 12 DOA tests)	12 70 09 70 00
SN 8.1	See Now Malaria	14 05 02 02 00
SN 8.2/SN 8.3	See Now Dengue virus IgG/IgM / NS1 Ag.	15 04 80 11 00
SN 9.1	See Now Tuberculosis	15 01 07 03 00
SN 9.2	See Now Salmonella IgG/IgM	15 01 10 03 00
TM 11.1	Trust Me Tetanus Ab.	15 01 40 09 00
SN 12.1	See Now Alcohol	12 09 02 07 00

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