

CAMP MEDICA DISTRIBUTION RO16768740

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DECLARAȚIE DE CONFORMITATE

În conformitate cu Anexa III din Directiva 98/79/CE pentru dispozitivele medicale de diagnostic in vitro a Consiliului European, noi

◆ **Producător** **Camp Medica Distribution SRL**
Str. Stanei nr. 29, Sector 4, București – România

declarăm pe propria răspundere că următoarele dispozitive medicale IVD

◆ **Denumire produs** teste rapide **See Now** de diagnostic in vitro – conform anexa,

îndeplinesc prevederile Directivei Europene 98/79/CE privind dispozitivele medicale pentru diagnostic in vitro, care li se aplică.

◆ **Cereri** Directiva Europeană nr. 98/79/CE din 27 Octombrie a
Parlamentului European pentru dispozitive medicale de diagnostic in vitro

◆ **Evaluarea conformității** Anexa III (din Directiva Europeană 98/79/CE), alineatele 2 - 5

◆ **Clasificare** dispozitive medicale pentru diagnostic in vitro -
Cod EDMA: 11 70 /12 70 / 15 70

◆ **Aplicarea Standardelor** 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

Camp Medica Distribution are implementat si certificat sistemul de management al calitatii conform cerintelor standardului **SR EN ISO 13485: 2012** (certificat seria DM, nr. 1002)

◆ **Locul, Data eliberării** București – România, 20.01.2017

Director management calitate
Dr. Ing. Carolina Constantin

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Anexa – teste rapide See Now

COD	Nume produs	EDMS	Clasa risc
SN 1.1/ SN 1.2	See Now hCG (Chorionic Gonadotropin)	12 70 05 02 00	Risc scazut
SN 1.3/ SN 1.4	See Now LH (leuteinizing hormone)	12 70 05 04 00	Risc scazut
SN 1.5/ SN 1.6	See Now FSH (follicle stimulating hormone)	12 70 05 01 00	Risc scazut
SN 2.2/ SN 2.2'	See Now H. Pylori (antibody / antigen)	15 70 01 02 00	Risc scazut
SN 3.1/ SN 3.2	See Now AFP-Alpha Fetoprotein	12 70 03 90 00	Risc scazut
SN 3.3/ SN 3.4	See Now CEA-Carcinoma Embryonic Antigen	12 70 03 90 00	Risc scazut
SN 3.7	See Now FOB (Fecal Occult Blood)	11 70 03 01 00	Risc scazut
SN 4.1/ SN 4.2	See Now Syphilis	15 70 01 05 00	Risc scazut
SN 4.3/ SN 4.4	See Now Gonorrhea	15 70 01 90 00	Risc scazut
SN 6.1	See Now Troponin I	12 70 13 03 00	Risc scazut
SN 6.2	See Now Myoglobin	12 70 13 02 00	Risc scazut
SN 6.3	See Now CK-MB	12 70 13 01 00	Risc scazut
SN 6.X.3	See Now cardiac panel (cTnl, CKMB, Myo)	12 70 13	Risc scazut
SN 7.1	See Now Amphetamine (AMP)	12 70 09 01 00	Risc scazut
SN 7.2	See Now Barbiturate (BAR)	12 70 09 03 00	Risc scazut
SN 7.3	See Now Benzodiazepine (BZD)	12 70 09 04 00	Risc scazut
SN 7.4	See Now Cocaine (COC)	12 70 09 06 00	Risc scazut
SN 7.5	See Now Methylenedioxy-methamphetamine(MDMA)	12 70 09 90 00	Risc scazut
SN 7.6	See Now Methamphetamine (MET)	12 70 09 90 00	Risc scazut
SN 7.7	See Now Morphine (MOP)	12 70 09 08 00	Risc scazut
SN 7.8	See Now Methadone (MTD)	12 70 09 07 00	Risc scazut
SN 7.9	See Now Opiate (OPI)	12 70 09 08 00	Risc scazut
SN 7.10	See Now Tricyclic Antidepressants (TCA)	12 70 09 10 00	Risc scazut
SN 7.11	See Now Marijuana (THC)	12 70 09 05 00	Risc scazut
SN 7.12	See Now Phencyclidine (PCP)	12 70 09 09 00	Risc scazut
SN 7.13	See Now Buprenorphine (BUP)	12 70 09 90 00	Risc scazut
SN 7.14	See Now Oxycodone (OXY)	12 70 09 90 00	Risc scazut
SN 7.15	See Now Propoxyphene (POX)	12 70 09 90 00	Risc scazut
SN 7.16	See Now Tramadol (TRA)	12 70 09 90 00	Risc scazut
SN 7.17	See Now Marijuana synthetic (K2)	12 70 09 90 00	Risc scazut
SN 7.X.2 – SN 7.X.12	See Now DOA panels (2 – 12 DOA tests)	12 70 09 70 00	Risc scazut
SN 8.1	See Now Malaria pf	14 05 02 02 00	Risc scazut
SN 8.2	See Now Malaria pf/pv Ag	14 05 02 02 00	Risc scazut
SN 8.2	See Now Dengue virus IgG/IgM Ab	15 04 80 11 00	Risc scazut
SN 8.3	See Now Dengue virus NS1 Ag	15 04 80 11 00	Risc scazut
SN 9.1	See Now Tuberculosis	15 01 07 03 00	Risc scazut
SN 9.2	See Now Salmonella IgG/IgM	15 01 10 03 00	Risc scazut

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