



C E R T I F I C A T

SRAC certifică organizația/ certifies the organisation

CAMP MEDICA DISTRIBUTION S.R.L.

Str. Stanei, nr. 29, sector 4, București

**pentru următoarele activități/
for the following fields of activities**

Producție și comercializare dispozitive medicale de diagnostic in vitro (IVD): Reactivi și produse reactive, calibranți și materiale de control pentru: Chimie Clinică, Imunochimie (Imunologie), Hematologie/Hemostază/Imunohematologie, Microbiologie, Imunologie Infecțioasă

Production and sale of in vitro diagnostic medical devices (IVD): reagents and reactive products, calibrators and control materials for: Clinical Chemistry, Immunochemistry (Immunology), Hematology / Haemostasis / Imunohematology, Microbiology, Infectious Immunology

că are implementat și menține un
sistem de managementul calității
conform condițiilor din standardul

which has implemented and maintains a
quality management system
which fulfils the requirements of the standard

EN ISO 13485:2016



Valabilitatea certificatului este condiționată de
efectuarea supravegheților anuale până la data de:



11-
2020

11-
2021

nr. certificat/ certificate registration no. **118**

data inițială a certificării/ initial certification date **15 noiembrie 2019**

data recertificării/ reissuing date -

data ultimei actualizări/ last update -

valabil până la/ valid until **14 noiembrie 2022** (cu condiția vizării anuale)

SRAC CERT SRL, Str. Vasile Pârvan Nr. 14, Sector 1, București www.srac.ro

Director General
Ing. Mihaela Cristea





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

SRAC as an IQNet Partner hereby states that the organization:

CAMP MEDICA DISTRIBUTION S.R.L.

Str. Stanei, nr. 29, sector 4, București

for the following scope:

Production and sale of in vitro diagnostic medical devices (IVD): reagents and reactive products, calibrators and control materials for: Clinical Chemistry, Immunochemistry (Immunology), Hematology / Haemostasis / Immunohematology, Microbiology, Infectious Immunology

has implemented and maintains a

Quality Management System

which fulfils the requirements of the following standard:

EN ISO 13485 : 2016

Issued on: 2019 - 11 - 15

First issued on: 2019 - 11 - 15

for the validity date, please refer to the original certificate issued by **SRAC***

Registration Number: RO - 118



Alex Stoichitoiu
President of IQNet

eng. Mihaela Cristea
SRAC General Manager



IQNet Partners:**

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Certification Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCBC Poland
Quality Austria Austria RR Russia SIGE México SII Israel SIQ Slovenia SIRIM QAS International Malaysia
SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey Vinçotte Belgium YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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

Quality Manager

Dr. Eng. Carolina Constantin