

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

VEDALAB
Rue de l'Expansion
ZAT du Londeau - Cerisé - B.P. 181
61006 Alençon cedex
France

for the scope

Chlamydia trachomatis immunochromatographic rapid test including positive and negative controls; immunochromatographic tests for PSA qualitative detection for self-testing use; immunochromatographic tests for PSA qualitative, quantitative and semi-quantitative detection with readers including positive and negative controls; immunochromatographic rapid tests for self-testing use (see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex IV – excluding Section 4 and 6 of the Council Directive 98/79/EC

of the European Parliament and of the Council of
27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

Valid from	2021-06-16
Valid until	2024-05-26
Registration no.	D1086900073
Report no.	P21-00644-203074
Stuttgart	2021-06-16


Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-247.10.05

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Product category	Product	Class
Chlamydia trachomatis immunochromatographic rapid test including positive and negative controls	CHLAMY-CHECK-1 including CHLAMYDIA positive control and CHLAMYDIA negative control REF 1001, 1001A, 1001B, 1001C, 1071,1071-10T, 1071-4, 1071-4-10T, 1071-MS-4, 1071-MS-4-10T CHLAMYDIA positive control REF V010, V010B CHLAMYDIA negative control REF V015B	List B, Annex II
Immunochromatographic tests for PSA qualitative detection	PSA-CHECK-1 qualitative test REF 8051A, 8051B, 8051C, 8081, 8081-10T PSA-CHECK-1 OK, qualitative test REF 8087, 8081B	List B, Annex II
Immunochromatographic tests for PSA qualitative detection for self-testing use	PROSTA-CHECK and its variants REF 8084, 8084D, 8084AO, 8084AV, 8084BE, 8184 PSA-CHECK-1 HOMETEST REF 8084AW, 8084AX, 8084AT PROSTATA SCHNELLTEST REF 8084T PSA Test REF 8084C SiNO PROSTATA REF 8084J PROST.A.TEST REF 8084BC Prostate PSA Test REF MV88006-PSA SELFCheck PROSTATE HEALTH TEST REF SCPSA1 PROSTATA PROSTA-Check REF 8084BI Check4 Prostate health REF 8084AG Prostatakrebsvorsorge Test REF 602071DE Prostaatankerpreventietest REF 602071NL Easy Home test Prostaat REF IMP-10030 CareStix home Prostatakrebsvorsorge REF 8084B Patris Health - PSA Home Test REF PATRIS-PSA-01	List B, Annex II
Immunochromatographic tests for PSA quantitative and semi-quantitative detection with rapid tests readers including positive and negative controls	PSA-CHECK-1 REF 8091, 8091-10T, 8091-S, 8091-S-10T, V040, V041, V045	List B, Annex II





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Immunochromatographic tests for quantitative determination with rapid tests readers of free Prostate Specific antigen (f-PSA) in plasma or serum samples for professional use	free PSA-CHECK-1 REF F8091, F8091-10T	List B, Annex II
FSH menopause rapid test for self-testing	FSH-CHECK-1 Strip REF 11037, 11036 Klimakterie FSH-CHECK-1REF 11037BI FSH-CHECK-1 cassette REF 11006C, 11076, 11076-4, 11076-MS-4 FSH-CHECK-1 Midstream, MENO-CHECK and its variants REF 11066, 11066-11, 11066-12, 11084, 11066AO, 11084AV SloNO MENOPAUSA REF 11066J FLOURISH MENOPAUSE TEST KIT REF 11066BK Check4 Menopause REF 11066AG Easy home Test Menopause REF IMP-10021 SELFCheck menopause test REF SCMEN2	Self-testing not Annex II
hCG pregnancy test for self-testing in whole blood	Check4 Pregnancy Whole blood test REF 3184AG SELFCheck Pregnancy Blood TEST REF SCPBT1 BABYCHECK-1 WB REF 3184 PREGNASURE REF VL3184BL Patris Health - WB Pregnancy Home Test REF PATRIS-HCGWB-01	Self-testing not Annex II





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hCG pregnancy test for self-testing device in urine	BABYCHECK-1 and its variants REF 3006A, 3006B, 3006C, 3060, 3076, 3076-4, 3076-MS-4 BABYCHECK Plus REF 3084 BABYCHECK Plus-10 REF 3084-10 MONO-TEST REF 3003 Evidence-10 and its variants REF 3066-10, 3061-12-10, 3061-11-10 Evidence and its variants REF 3060, 3066, 3061-11, 3061-12, 3066AO dr. bosshammer-hCG REF 3061-12-10B JUMBO zwangerschapstest REF 3061-11-10AY leidapharm zwangerschapstest REF 3061-11-10AZ Sanelco zwangerschapstest REF 3061-11-10BA APOTEX zwangerschapstest REF 3061-11-10BB SloNO GRAVIDANZA 1 TEST STICK REF 3066J SloNO GRAVIDANZA 2 TEST STICK REF 3066J-2 Graviditet Evidence REF 3066BI Check4 Pregnancy urine test REF 3066AG Easy Home test Zwangerschap REF IMP-10016 Check4 pregnancy Urine test+ REF 3084AG SELFCheck Pregnancy Urine Test REF SCPUT2	Self-testing not Annex II
hCG strip pregnancy test for self-testing in urine	Graviditet hCG STRIP REF 3037BI SloNO GRAVIDANZA 1 TEST STRISCIA REF 3037J Baby CHECK Strip Mini REF 3033 hCG STRIP-10 REF 3037B-10, 3037C-10 BB Test 10IU/L REF 3039B-10, 3039B-10-20T, 3039B-10-CEI, 3039B-10-UKR hCG STRIP, Babycheck Strip and its variants REF 3037B, 3037C, 3037B-1, 3037C-1 Baby CHECK QUICK REF 3033-1	Self-testing not Annex II



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Product category	Product	Class
Immunochromatographic test for detection of blood in faeces for self-testing	POLY-CHECK and its variants REF 4084, 4084AV, 4084AO, 4084BI FEC.O.TEST REF 4084BC SiONO COLON RETTO REF 4084J Check4 Bowel Health REF 4084AG Darmkrebsvorsorge test REF 272071DE Darmkankerpreventietest REF 272071NL Easy Home Test Ontlasting REF IMP-10029 CareStix Home Darmkrebsvorsorge REF 4084B Patris Health - FIT Home Test REF PATRIS-FIT-01	Self-testing not Annex II
LH ovulation rapid test for self-testing	L-CHECK-1 STRIP REF 5037 Agglossning L-CHECK-1 REF 5037BI SiONO OVULAZIONE STRISCIA REF 5037J L-CHECK-1 CASSETTE and its variants REF 5006A, 5006B, 5006C, 5076, 5076-4, 5076-MS-4 L-CHECK-1 MIDSTREAM and its variants REF 5066, 5066-11, 5084, 5084AV, 5066BI SiONO OVULAZIONE STICK REF 5066J Check4 Ovulation REF 5066AG Easy Home test Ovulatie REF IMP-10017	Self-testing not Annex II
Self-testing device for determination of human chorionic gonadotropin (hCG) level above 1000 IU/mL in urine to check the outcome of termination of pregnancy	Check4-hCG (hl) REF 3066-1000AG, 3067-1000AG CheckToP REF 3066-1000AI, 3067-1000AI	Self-testing not Annex II





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Product category	Product	Class
Self-testing rapid test for anti-borrelia IgM antibody detection in whole blood	Tik'Alert and its variants REF 70084, 70084B, 70084AO, 70084AV, 70184, 70084BI Borreliosis Test (Lyme) REF MV88488-BOR SELFCheck LYME DISEASE TEST REF SCLYM1 Check4 Tick Bite Borrelia REF 70084AG Easy home Test Lyme – Tekenbeet REF IMP-10018 Patris Health - Lyme Disease Home Test REF PATRIS-LYME-01	Self-testing not Annex II
Self-testing rapid test for detection of antibodies against helicobacter pylori bacteria in whole blood	PYLORI-Screen and its variants REF 17084, 17084B, 17084AO, 17084AV, 17184, 17084BI StONO HELICOBACTER PYLORI REF 17084J Helicobacter Test REF MV88150-HP Helicobacter pylori-test REF 262071NL Helicobacter pylori test REF 262071DE SELFCheck Stomach Ulcer test REF SCSUT1 Check4 Stomach Ulcers REF 17084AG Easy Home Test Maag-Pylori REF IMP-10028 Patris Health - Helicobacter pylori Home Test REF PATRIS-HP-01	Self-testing not Annex II
Self-testing rapid test for detection of hypothyroidism in whole blood	THYRO-Check and its variants REF 21084, 21084AO, 21084AV Thyroid test REF MV88587-THY SELFCheck THYROID HEALTH TEST REF SCTSH1 Sköldkörtel THYRO-Check REF 21084BI Check4 Under Active Thyroid REF 21084AG Easy Home test Schilddklier REF IMP-10033 Patris Health - Thyroid Function Home Test REF PATRIS-TSH-01	Self-testing not Annex II




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Product category	Product	Class
Self-testing rapid test for the detection of gluten intolerance	GLUTEN'ALARM and its variants REF 150084, 150084AO, 150084AV, 150084BI Gluten test REF MV88594-GLU SELFCheck GLUTEN SENSITIVITY TEST REF SCGLU1 Easy Home Test Glutenintolerantie REF IMP-10027 Check4 Gluten Intolerance REF 150084AG Gluten Test REF 790005DE Glutentest REF 790005NL Patris Health - Coeliac Disease Home Test REF PATRIS-TTG-01	Self-testing not Annex II
Self-testing rapid test for detection of iron deficiency in whole blood	FERRI-Check and its variants REF 25084, 25084AO, 25084AV, 25184, KST25084EP AnemiaTest REF MV88129-FER SELFCheck IRON LEVEL TEST REF SCFER1 Järnbrist FERRI-CHECK REF 25084BI Check4 Iron Deficiency Anaemia REF 25084AG Easy home Test Bloedarmoede REF IMP-10026 Patris Health - Anemia Home Test REF PATRIS-ANEM-01	Self-testing not Annex II
Self-testing rapid test for IgE detection in whole blood	ALLERGY-Check and its variants REF 18084, 18084AO, 18084AV, 18084BE, 18184 Allergy test REF MV88105-ALG SELFCheck ALLERGY TEST REF SCIGE1 ALLERGITEST ALLERGY-Check REF 18084BI Check4 Allergy REF 18084AG Easy Home test Allergie REF IMP-10006 Patris Health - Allergy Home Test REF PATRIS-ALRG-01	Self-testing not Annex II





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Self-testing rapid test for the assessment of tetanus protection	TETANOSTOP and its variants REF 92084, 92084AO, 92084AV SELFCheck TETANUS TEST REF SCTET1 Check4 Tetanus Protection REF 92084AG Easy Home Test Tetanus status REF IMP-10032 Patris Health - Tetanus Home Test REF PATRIS-TET-01	Self-testing not Annex II
Self-testing rapid test for the detection of group A beta-hemolytic streptococcus bacteria in throat infection	STREPA'LERT REF 6037, 6037BI, 6037AO, 6037AV Check4 Strep Throat REF 6037AG Easy home test Keelinfectie REF IMP-10031 Patris Health - Strep A Home Test REF PATRIS-STRPA-01	Self-testing not Annex II
Self-testing rapid test for the detection of antibodies against Syphilis (Treponema pallidum) in whole blood	SYPH-CHECK-1 REF 26084, 26184, 26084BI Syphilis Test REF MV87979-SYP VENERIS Test Rapid Sifilis REF 26084BG SELFCheck SYPHILIS TEST REF SCSYP1 Check4 Syphilis REF 26084AG Easy Home test Syfilis REF IMP-10020 Patris Health - Syphilis Home Test REF PATRIS-SYPH-01, PATRIS-SYPH-02	Self-testing not Annex II
Self-testing rapid test for the detection of C-reactive protein (CRP) in whole blood	CRP-Screen REF 34084, 34184, 34084AO, 34084BI Inflammation CRP Test REF MV88020-CRP SELFCheck CRP TEST REF SCCRP1 C-reaktives Protein (CRP) Test REF 311071DE C-reactief proteinetest (CRP) REF 311071NL Check4 inflammation and infection REF 34084AG Easy Home test CRP-Ontsteking REF IMP-10025 Patris Health - CRP Home Test REF PATRIS-CRP-01	Self-testing not Annex II





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Strip immunochromatographic rapid test for self-testing of albumin in urine	M-ALBU-CHECK-1 Strip REF 27037, 27037AO, 27037AV, 27037BE, 27037BI SloNO ALBUMINA TEST REF 27037J SELFCheck KIDNEY HEALTH TEST REF SCALB1 Check4 Kidney health REF 27037AG Patris Health - Kidney Function Home Test REF PATRIS-ALBU-01	Self-testing not Annex II
Self-testing assessment of liver physiological status in whole blood	LIVER-SCREEN REF 999984W-3L, 999984W-3L-AO SELFCheck LIVER HEALTH TEST REF SCENZ1 LEVERTEST LIVER-SCREEN REF 999984W-3L-BI Check4 Liver health REF 999984W-3L-AG Easy home test Lever – Functie REF IMP-10024 Patris Health - Liver Function Home Test REF PATRIS-LVR-01	Self-testing not Annex II
Self-testing test for the detection of rotavirus and/or adenovirus in faeces	ROTADENO-Screen REF 302984, 302984BI Patris Health - Rotavirus-Adenovirus Home Test REF PATRIS-RTAD-01	Self-testing not Annex II
Self-testing rapid test for the detection of SARS-CoV-2 antigen in nasal swab sample	COVID-19-CHECK-1 ANTIGEN REF 200074-4, PATRIS-COVID19-AG SELFCheck COVID-19 Antigen Test REF SCCOV2	Self-testing not Annex II





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