

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 | 2019-01-24 |
| Valid until | 2020-11-02 |
| Registration no. | D1086900062 |
| Report no. | P18-01009-138699 |
| Stuttgart | 2019-01-24 |


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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Attachment of the certificate

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| Product category | Product | Class |
|--|---|------------------------------|
| FSH menopause rapid test for self-testing | FSH-CHECK-1 Strip, REF 11037, 11036 Klimakterie FSH-CHECK-1, REF 11037BI FSH-CHECK-1 cassette, REF 11006C, 11076, 11076-4, 11076-MS-4 FSH-CHECK-1 Midstream MENO-CHECK [®] , REF 11066, 11066-11, 11066-12, 11084, 11066AO, 11084AV SloNO MENOPAUSA, REF 11066J | Self-testing not Annex II |
| hCG pregnancy test for self-testing device | BABYCHECK-1 [®] , REF 3006A, 3006B, 3006C, 3076, 3076-4, 3076-MS-4 MONO-TEST, REF 3003 Evidence-10, REF 3066-10, 3061-12-10, 3061-11-10 EVIDENCE, 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 Babycheck Plus-10, REF 3084-10 Babycheck Plus [®] , REF 3084 BABYCHECK-1, REF 3060 SloNO GRAVIDANZA 1 TEST, REF 3066J SloNO GRAVIDANZA 2 TESTS, REF 3066J-2 Graviditet Evidence, REF 3066BI | Self-testing not Annex II |
| hCG strip pregnancy test for self-testing | hCG STRIP, REF 3037B, 3037C Graviditet hCG STRIP, REF 3037BI Babycheck [®] strip, REF 3037B-1, 3037C-1, 3037L SloNO GRAVIDANZA 1 TEST STRISCIA, REF 3037J Baby CHECK [®] Strip Mini, REF 3033 Baby CHECK [®] QUICK, REF 3033-1 hCG STRIP-10, REF 3037B-10, 3037C-10 BB TEST [®] 10IU/L, REF 3039B-10 | Self-testing not Annex II |




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| Product category | Product | Class |
|--|---|------------------------------|
| Immunochematographic test for detection of blood in faeces for self-testing | POLY-Check®, REF 4084, 4084L, 4084AR, 4084AV, 4084AO POLY-Check Darmkrebsvorsorgetest, REF 4084B, 4084AT FEC.O.TEST®, REF 4084BC Darmkrebsvorsorgetest Heumann, REF 4084I SiONO COLON RETTO, REF 4084J YesNo Självttest Dolt Bold, REF 4084AL | Self-testing not Annex II |
| LH ovulation rapid test for self-testing | L-CHECK-1 Strip, REF 5037, 5037L Agglossning L-CHECK-1, REF 5037BI SiONO OVULAZIONE STRISCIA, REF 5037J L-CHECK-1 Cassette, REF 5006A, 5006B, 5006C, 5076, 5076-4, 5076-MS-4 L-CHECK-1 Midstream, REF 5066, 5066-11, 5084, 5084AV Babycheck Plus® ovulation test, REF 5060 SiONO OVULAZIONE STICK, REF 5066J L-CHECK-1 MIDSTREAM, REF 5066BI | 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 |
| Self-testing rapid test for anti-borrelia IgM antibody detection in whole blood | TIK'ALERT®, REF 70084, 70084B, 70084AO, 70084F, 70084AV, 70184, 70084BI Alere™ Lyme Home Test, REF 70084AE Borreliosis Test (Lyme), REF MV88488-BOR SELFCheck LYME SCREEN, REF SCLYM1 | Self-testing not Annex II |




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| Product category | Product | Class |
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| Self-testing rapid test for detection of antibodies against helicobacter pylori bacteria in whole blood | PYLORI-Screen® REF 17084, 17084B, 17084AO, 17084AR, 17084AV, 17184, 17084BI Alere™ H-pylori Home Test, REF 17084AE SiONO HELICOBACTER PYLORI, REF 17084J Helicobacter Test, REF MV88150-HP | Self-testing not Annex II |
| Self-testing rapid test for detection of hypothyroidism in whole blood | THYRO-Check® REF 21084, 21084AO, 21084AR, 21084AV Alere™ Thyroïde Home Test, REF 21084AE Thyroid test REF MV88587-THY SELFCheck THYROID HEALTH, REF SCTSH1 Sköldkörtel THYRO-Check, REF 21084BI | Self-testing not Annex II |
| Self-testing rapid test for detection of iron deficiency in whole blood | FERRI-Check®, REF 25084, 25084AO, 25084AV, 25184, KST25084EP ApoLife® EISEN-FER-TEST, REF 25084BD Alere™ Fer Home Test, REF 25084AE Anemia Test, REF MV88129-FER SELFCheck IRON LEVEL, REF SCFER1 Jänbrist FERRI-CHECK REF 25084BI | Self-testing not Annex II |
| Self-testing rapid test for IgE detection in whole blood | ALLERGY-Check®, REF 18084, 18084AO, 18084AV, 18084BE, 18184 Alere™ Allergie Home Test, REF 18084AE Allergy Test, REF MV88105-ALG SELFCheck ALLERGY, REF SCIGE1 ALLERGITEST ALLERGY-Check REF 18084BI | Self-testing not Annex II |
| Self-testing rapid test for the assessment of tetanus protection | TETANOSTOP®, REF 92084, 92084AO, 92084AV Alere™ Tétanos Home Test, REF 92084AE SELFCheck TETANUS, REF SCTET1 | Self-testing not Annex II |




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| Product category | Product | Class |
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| Self-testing rapid test for the detection of antibodies against Syphilis (<i>Treponema pallidum</i>) in whole blood | Syph-Check-1 [®] , REF 26084, 26184, 26084AV Syphilis Test, REF MV87979-SYP VENERIS Test Rapid Sifilis, REF 26084BG SELFCheck SYPHILIS REF SCSYP1 | 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, REF SCCRP1 | Self-testing not Annex II |
| Self-testing rapid test for the detection of gluten intolerance | GLUTEN'ALARM [®] , REF 150084, 150084AV, 150084BI Gluten test, REF MV88594-GLU SELFCheck GLUTEN SENSITIVITY, REF SCGLU1 | 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 | Self-testing not Annex II |
| Self-testing whole blood rapid test for assessment of liver physiological status | LIVER-Screen [®] , REF 999984W-3L, 999984W-3L-AO SELFCheck LIVER HEALTH, REF SCENZ1 LEVERTEST LIVER-SCREEN, REF 999984W-3L-BI | Self-testing not Annex II |
| Strip immunochromatographic rapid test for self-testing of albumin in urine | M-ALBU-CHECK-1 Strip, REF 27037, 27037L, 27037AO, 27037AV, 27037BE SloNO ALBUMINA TEST, REF 27037J Alere™ Albumine Home Test, REF 27037AE SELFCheck KIDNEY HEALTH, REF SCALB1 | Self-testing not Annex II |
| Chlamydia trachomatis immunochromatographic rapid test including positive and negative controls | CHLAMY-CHECK-1, REF 1001, 1002, 1003, 1071, 1072, 1073, 1071-4, 1071-MS-4 CHLAMYDIA positive control REF V010, V010B CHLAMYDIA negative control REF V015B | List B, Annex II |




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|---|--|------------------|
| Immunochematographic tests for free PSA quantitative and semi-quantitative detection with rapid tests readers | Free PSA-CHECK-1, REF F8091, F8091-10T | List B, Annex II |
| Immunochematographic tests for PSA qualitative detection | PSA-CHECK-1 qualitative test, REF 8051A, 8051B, 8051C, 8081 PSA-CHECK-1 OK, qualitative test, REF 8087, 8081B | List B, Annex II |
| Immunochematographic tests for PSA qualitative detection for self-testing use | PROSTA-CHECK® REF 8084, 8084D, 8084L, 8084AO, 8084AR, 8084AV; 8084BE, 8184 PSA-CHECK-1 HOMETEST, REF 8084AW, 8084AX, 8084B, 8084AT PROSTATA SCHNELLTEST, REF 8084T PSA Test, REF 8084C ApoLife® PROSTATA-PSA-TEST, REF 8084BD SloNO PROSTATA , REF 8084J YesNo Kotitesti Prostata, REF 8084AN YesNo Självtest Prostata, REF 8084AL Alere™ Prostate Home Test, REF 8084AE PROST.A.TEST, REF 8084BC Prostate PSA Test, MV88006-PSA SELFCheck PROSTATE HEALTH, REF SCPSA1 PROSTATA PROSTA-Check, REF 8084BI | List B, Annex II |
| Immunochematographic tests for PSA quantitative and semi-quantitative detection with rapid tests readers including positive and negative controls | PSA-CHECK-1, quantitative and semi-quantitative detection with rapid tests readers including positive and negative controls, REF 8091, 8091-S PSA medium positive control, REF V040 PSA strong positive control, REF V041 PSA negative control, REF V045 | List B, Annex II |




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