

# 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       | 2021-01-18       |
| Valid until      | 2024-05-26       |
| Registration no. | D1086900071      |
| Report no.       | P20-01290-195851 |
| Stuttgart        | 2021-01-18       |

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

**Attachment of the certificate**

**No. D1086900071**

Date 2021-01-18

Page 1 of 7

| 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<br>CHLAMYDIA positive control REF V010, V010B<br>CHLAMYDIA negative control REF V015B  | List B,<br>Annex II |
| Immunochromatographic tests for PSA qualitative detection  | PSA-CHECK-1 qualitative test REF 8051A, 8051B, 8051C, 8081, 8081-10T<br>PSA-CHECK-1 OK, qualitative test REF 8087, 8081B   | List B,<br>Annex II |
| Immunochromatographic tests for PSA qualitative detection for self-testing use   | PROSTA-CHECK and its variants REF 8084, 8084D, 8084AO, 8084AV, 8084BE, 8184<br>PSA-CHECK-1 HOMETEST REF 8084AW, 8084AX, 8084AT<br>PROSTATA SCHNELLTEST REF 8084T<br>PSA Test REF 8084C<br>SiONO PROSTATA REF 8084J<br>PROST.A.TEST REF 8084BC<br>Prostate PSA Test REF MV88006-PSA<br>SELFCheck PROSTATE HEALTH TEST REF SCPSA1<br>PROSTATA PROSTA-Check REF 8084BI<br>Check4 Prostate health REF 8084AG<br>Prostatakrebsvorsorge Test REF 602071DE<br>Prostaatankerpreventietest REF 602071NL<br>Easy Home test Prostaat REF IMP-10030<br>CareStix home Prostatakrebsvorsorge REF 8084B | List B,<br>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,<br>Annex II |



  
 Head of Certification Body

**Attachment of the certificate**

**No. D1086900071**

Date 2021-01-18

Page 2 of 7

| Product category  | Product  | Class                     |
|---|--|---------------------------|
| 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<br>Klimakterie FSH-CHECK-1REF 11037BI<br>FSH-CHECK-1 cassette REF 11006C, 11076, 11076-4, 11076-MS-4<br>FSH-CHECK-1 Midstream, MENO-CHECK and its variants REF 11066, 11066-11, 11066-12, 11084, 11066AO, 11084AV<br>SiONO MENOPAUSA REF 11066J<br>FLOURISH MENOPAUSE TEST KIT REF 11066BK<br>Check4 Menopause REF 11066AG<br>Easy home Test Menopause REF IMP-10021<br>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<br>SELFCheck Pregnancy Blood TEST REF SCPBT1<br>BABYCHECK-1 WB REF 3184<br>PREGNASURE REF VL3184BL  | Self-testing not Annex II |



  
 Head of Certification Body

**Attachment of the certificate**

**No. D1086900071**

Date 2021-01-18

Page 3 of 7

| Product category                                    | Product   | Class                     |
|---|---|---------------------------|
| 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<br>BABYCHECK Plus REF 3084<br>BABYCHECK Plus-10 REF 3084-10<br>MONO-TEST REF 3003<br>Evidence-10 and its variants REF 3066-10, 3061-12-10, 3061-11-10<br>Evidence and its variants REF 3060, 3066, 3061-11, 3061-12, 3066AO<br>dr. bosshammer-hCG REF 3061-12-10B<br>JUMBO zwangerschapstest REF 3061-11-10AY<br>leidapharm zwangerchapstest REF 3061-11-10AZ<br>Sanelco zwangerschapstest REF 3061-11-10BA<br>APOTEX zwangerschapstest REF 3061-11-10BB<br>SloNO GRAVIDANZA 1 TEST STICK REF 3066J<br>SloNO GRAVIDANZA 2 TEST STICK REF 3066J-2<br>Graviditet Evidence REF 3066BI<br>Check4 Pregnancy urine test REF 3066AG<br>Easy Home test Zwangerschap REF IMP-10016<br>Check4 pregnancy Urine test+ REF 3084AG<br>SELFCheck Pregnancy Urine Test REF SPCUT2 | Self-testing not Annex II |
| hCG strip pregnancy test for self-testing in urine  | Graviditet hCG STRIP REF 3037BI<br>SloNO GRAVIDANZA 1 TEST STRISCIA REF 3037J<br>Baby CHECK Strip Mini REF 3033<br>hCG STRIP-10 REF 3037B-10, 3037C-10<br>BB Test 10IU/L REF 3039B-10, 3039B-10-20T, 3039B-10-CEI, 3039B-10-UKR<br>hCG STRIP, Babycheck Strip and its variants REF 3037B, 3037C, 3037B-1, 3037C-1<br>Baby CHECK QUICK REF 3033-1  | Self-testing not Annex II |



  
 Head of Certification Body

**Attachment of the certificate**

**No. D1086900071**

Date 2021-01-18

Page 4 of 7

| 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<br>FEC.O.TEST REF 4084BC<br>SloNO COLON RETTO REF 4084J<br>Check4 Bowel Health REF 4084AG<br>Darmkrebsvorsorge test REF 272071DE<br>Darmkankerpreventietest REF 272071NL<br>Easy Home Test Ontlasting REF IMP-10029<br>CareStix Home Darmkrebsvorsorge REF 4084B   | Self-testing<br>not Annex II |
| LH ovulation rapid test for self-testing   | L-CHECK-1 STRIP REF 5037<br>Agglossning L-CHECK-1 REF 5037BI<br>SloNO OVULAZIONE STRISCIA REF 5037J<br>L-CHECK-1 CASSETTE and its variants REF 5006A, 5006B, 5006C, 5076, 5076-4, 5076-MS-4<br>L-CHECK-1 MIDSTREAM and its variants REF 5066, 5066-11, 5084, 5084AV, 5066BI<br>SloNO OVULAZIONE STICK REF 5066J<br>Check4 Ovulation REF 5066AG<br>Easy Home test Ovulatie REF IMP-10017 | Self-testing<br>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<br>CheckToP REF 3066-1000AI, 3067-1000AI   | Self-testing<br>not Annex II |
| 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<br>Borreliosis Test (Lyme) REF MV88488-BOR<br>SELFCheck LYME DISEASE TEST REF SCLYM1<br>Check4 Tick Bite Borrelia REF 70084AG<br>Easy home Test Lyme – Tekenbeet REF IMP-10018   | Self-testing<br>not Annex II |



*[Signature]*  
Head of Certification Body

**Attachment of the certificate**

**No. D1086900071**

Date 2021-01-18

Page 5 of 7

| Product category  | Product  | Class                        |
|---|--|------------------------------|
| 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<br>SiONO HELICOBACTER PYLORI REF 17084J<br>Helicobacter Test REF MV88150-HP<br>Helicobacter pylori-test REF 262071NL<br>Helicobacter pylori test REF 262071DE<br>SELFCheck Stomach Ulcer test REF SCSUT1<br>Check4 Stomach Ulcers REF 17084AG<br>Easy Home Test Maag-Pylori REF IMP-10028 | Self-testing<br>not Annex II |
| Self-testing rapid test for detection of hypothyroidism in whole blood                                  | THYRO-Check and its variants REF 21084, 21084AO, 21084AV<br>Thyroid test REF MV88587-THY<br>SELFCheck THYROID HEALTH TEST REF SCTSH1<br>Sköldkörtel THYRO-Check REF 21084BI<br>Check4 Under Active Thyroid REF 21084AG<br>Easy Home test Schilddklier REF IMP-10033  | Self-testing<br>not Annex II |
| Self-testing rapid test for the detection of gluten intolerance   | GLUTEN'ALARM and its variants REF 150084, 150084AO, 150084AV, 150084BI<br>Gluten test REF MV88594-GLU<br>SELFCheck GLUTEN SENSITIVITY TEST REF SCGLU1<br>Easy Home Test Glutenintolerantie REF IMP-10027<br>Check4 Gluten Intolerance REF 150084AG<br>Gluten Test REF 790005DE<br>Glutentest REF 790005NL  | Self-testing<br>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<br>AnemiaTest REF MV88129-FER<br>SELFCheck IRON LEVEL TEST REF SCFER1<br>Järnbrist FERRI-CHECK REF 25084BI<br>Check4 Iron Deficiency Anaemia REF 25084AG<br>Easy home Test Bloedarmoede REF IMP-10026  | Self-testing<br>not Annex II |



  
 Head of Certification Body

**Attachment of the certificate**

**No. D1086900071**

Date 2021-01-18

Page 6 of 7

| Product category   | Product  | Class                     |
|--|--|---------------------------|
| Self-testing rapid test for IgE detection in whole blood   | ALLERGY-Check and its variants REF 18084, 18084AO, 18084AV, 18084BE, 18184<br>Allergy test REF MV88105-ALG<br>SELFCheck ALLERGY TEST REF SCIGE1<br>ALLERGITEST ALLERGY-Check REF 18084BI<br>Check4 Allergy REF 18084AG<br>Easy Home test Allergie REF IMP-10006  | Self-testing not Annex II |
| Self-testing rapid test for the assessment of tetanus protection   | TETANOSTOP and its variants REF 92084, 92084AO, 92084AV<br>SELFCheck TETANUS TEST REF SCTET1<br>Check4 Tetanus Protection REF 92084AG<br>Easy Home Test Tetanus status REF IMP-10032   | 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<br>Check4 Strep Throat REF 6037AG<br>Easy home test Keelinfectie REF IMP-10031  | 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<br>Syphilis Test REF MV87979-SYP<br>VENERIS Test Rapid Sifilis REF 26084BG<br>SELFCheck SYPHILIS TEST REF SCSYP1<br>Check4 Syphilis REF 26084AG<br>Easy Home test Syfilis REF IMP-10020   | 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<br>Inflammation CRP Test REF MV88020-CRP<br>SELFCheck CRP TEST REF SCCRP1<br>C-reaktives Protein (CRP) Test REF 311071DE<br>C-reactief proteinetest (CRP) REF 311071NL<br>Check4 inflammation and infection REF 34084AG<br>Easy Home test CRP-Ontsteking REF IMP-10025 | Self-testing not Annex II |



  
 Head of Certification Body

**Attachment of the certificate**

**No. D1086900071**

Date 2021-01-18

Page 7 of 7

| Product category   | Product   | Class                     |
|--|---|---------------------------|
| Strip immunochromatographic rapid test for self-testing of albumin in urine  | M-ALBU-CHECK-1 Strip REF 27037, 27037AO, 27037AV, 27037BE, 27037BI<br>SiONO ALBUMINA TEST REF 27037J<br>SELFCheck KIDNEY HEALTH TEST REF SCALB1<br>Check4 Kidney health REF 27037AG                                       | Self-testing not Annex II |
| Self-testing assessment of liver physiological status in whole blood         | LIVER-SCREEN REF 999984W-3L, 999984W-3L-AO<br>SELFCheck LIVER HEALTH TEST REF SCENZ1<br>LEVERTEST LIVER-SCREEN REF 999984W-3L-BI<br>Check4 Liver health REF 999984W-3L-AG<br>Easy home test Lever – Functie REF IMP-10024 | Self-testing not Annex II |
| Self-testing test for the detection of rotavirus and/or adenovirus in faeces | ROTADENO-Screen REF 302984, 302984BI  | Self-testing not Annex II |



  
Head of Certification Body