

# 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       | 2022-05-23       |
| Valid until      | 2025-05-26       |
| Registration no. | D1086900078      |
| Report no.       | P22-00365-240843 |
| Stuttgart        | 2022-05-23       |

  
Head of Certification Body



**Attachment of the certificate**

**No. D1086900078**

Date 2022-05-23

Page 1 of 12

| 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, 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, Annex II |
| Immunochromatographic tests for PSA qualitative detection for self-testing use                  | PROSTA-CHECK and its variants (REF 8084, 8084D, 8084AO, 8084AV, 8084BE, 8184, 8084/IT, 8084/IT1, 8084/PT, 8084/HR, 8084/DE, 8084/ES, 8084/GR, 8084/BG, 8084/RO, 8084/IE)<br>PSA-CHECK-1 HOMETEST (REF 8084AW, 8084AX, 8084AT, 8084/HU, 8084/CZ, 8084/SK)<br>PROSTATA SCHNELLTEST (REF 8084T)<br>PSA Test (REF 8084C)<br>SloNO 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, 8084/DK, 8084/DK1)<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)<br>Patris Health - PSA Home Test (REF PATRIS-PSA-01)<br>POLONORD ADESTE Test Prostata (REF ADESTE-PSA1)<br>Self Care Test rapid afectiuni ale prostatei (PSA) (REF SC019 )<br>PROSTA SelfTest (REF 8084AO2) | List B, Annex II |



  
 Head of Certification Body

**Attachment of the certificate**

**No. D1086900078**

Date 2022-05-23

Page 2 of 12

| Product category   | Product   | Class                     |
|--|---|---------------------------|
| Immunochematographic 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, 8091-S/HU, V040, V041, V045)   | List B, Annex II          |
| Immunochematographic 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          |
| LH ovulation rapid test for self-testing   | L-CHECK-1 STRIP (REF 5037, 5037/DE, 5037/ES, 5037/GR, 5037/BG, 5037/RO)<br>Agglossning L-CHECK-1 (REF 5037BI)<br>SIoNO OVULAZIONE STRISCIA (REF 5037J)<br>BARZA Test de ovulatie (REF SC008)<br>L-CHECK-1 CASSETTE and its variants (REF 5006A, 5006B, 5006C, 5076, 5076-4, 5076-MS-4, 5076/DE, 5076/ES, 5076/GR, 5076/BG, 5076/RO)<br>L-CHECK-1 MIDSTREAM and its variants (REF 5066, 5066-11, 5084, 5084AV, 5066BI, 5066/IT, 5066/PT, 5066/DE, 5066/ES, 5066/GR, 5066/BG, 5066/RO)<br>SIoNO OVULAZIONE STICK (REF 5066J)<br>Check4 Ovulation (REF 5066AG)<br>Easy Home test Ovulatie (REF IMP-10017)<br>POLONORD ADESTE Test ovulazione (REF ADESTE-OVU1) | Self-testing not Annex II |



  
 Head of Certification Body

**Attachment of the certificate**

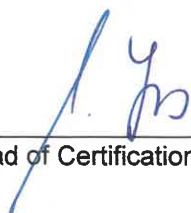
**No. D1086900078**

Date 2022-05-23

Page 3 of 12

| Product category                                    | Product   | Class                        |
|---|---|------------------------------|
| hCG pregnancy test for self-testing in whole blood  | BABYCHECK-1 WB and its variants (REF 3184, 3184/PT, 3184/HU, 3184/CZ, 3184/SK, 3184/HR, 3184/DE, 3184/ES, 3184/GR, 3184/BG, 3184/RO)<br>Check4 Pregnancy Whole blood test (REF 3184AG)<br>SELFCheck Pregnancy Blood TEST (REF SCPBT1)<br>PREGNASURE (REF VL3184BL)<br>Patris Health - WB Pregnancy Home Test (REF PATRIS-HCGWB-01)<br>POLONORD ADESTE Test Gravidanza su sangue (REF ADESTE-WBP1)<br>BARZA Test de sarcina din sange (REF SC007)  | Self-testing<br>not Annex II |
| 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, 3076-4/DE, 3076-4/ES, 3076-4/GR, 3076-4/BG, 3076-4/RO)<br>MONO-TEST (REF 3003)<br>BABYCHECK Plus (REF 3084)<br>BABYCHECK Plus-10 (REF 3084-10)<br>Check4 pregnancy Urine test+ (REF 3084AG)<br>Evidence-10 and its variants (REF 3066-10, 3061-12-10, 3061-11-10, 3066-10/PT, 3066-10/DE, 3066-10/ES, 3066-10/GR, 3066-10/BG, 3066-10/RO)<br>Evidence and its variants (REF 3060, 3066, 3061-11, 3061-12, 3066AO, 3066/BM, 3066/IT, 3066/HR, 3066/DE, 3066/ES, 3066/GR, 3066/BG, 3066/RO)<br>BABYCHECK Pregnancy Midstream Test (REF 3066/GR1, 3066-2T/GR1, 3066-10/GR1)<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) | Self-testing<br>not Annex II |



  
 Head of Certification Body

**Attachment of the certificate**

**No. D1086900078**

Date 2022-05-23

Page 4 of 12

| Product category   | Product  | Class                        |
|--|--|------------------------------|
| hCG pregnancy test for self-testing device in urine  | Check4 Pregnancy urine test (REF 3066AG)<br>Easy Home test Zwangerschap (REF IMP-10016)<br>SELFCheck Pregnancy Urine Test (REF SCPUT2)<br>POLONORD ADESTE Test precoce di gravidanza (REF ADESTE-HCG1)<br>BARZA Test de sarcina clasic caseta (REF SC002 )<br>BARZA Test de sarcina clasic stilou (REF SC003)<br>BARZA Test de sarcina ultrasensibil stilou (REF SC006)<br>BABYCHECK-1-10 (REF 3076-10)<br>Barza Test de sarcina ultrasensibil caseta (REF SC005)  | Self-testing<br>not Annex II |
| hCG strip pregnancy test for self-testing in urine   | Baby CHECK Strip Mini (REF 3033)<br>Baby CHECK QUICK (REF 3033-1)<br>hCG STRIP, Babycheck Strip and its variants (REF 3037B, 3037C, 3037B-1, 3037C-1, 3037B/DE, 3037B/ES, 3037B/GR, 3037B/BG, 3037B/RO)<br>Graviditet hCG STRIP (REF 3037BI)<br>SiNO GRAVIDANZA 1 TEST STRISCIA (REF 3037J)<br>hCG STRIP-10 (REF 3037B-10, 3037C-10)<br>Babycheck Strip-10 (REF 3037B-10/DE, 3037B-10/ES, 3037B-10/GR, 3037B-10/BG, 3037B-10/RO)<br>BB Test 10IU/L (REF 3039B-10, 3039B-10-20T, 3039B-10-CEI, 3039B-10-UKR)<br>BARZA Test de sarcina clasic banda (REF SC001)<br>BARZA Test de sarcina ultrasensibil banda (REF SC004) | 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 (hI) (REF 3066-1000AG, 3067-1000AG)<br>CheckToP (REF 3066-1000AI, 3067-1000AI)<br>Check4 hCG-1000 (REF 3076-1000AG)   | Self-testing<br>not Annex II |



  
 Head of Certification Body



Attachment of the certificate

No. D1086900078

Date 2022-05-23

Page 5 of 12

| Product category                          | Product  | Class                        |
|---|--|------------------------------|
| FSH menopause rapid test for self-testing | FSH-CHECK-1 Strip (REF 11037, 11036, 11037/DE, 11037/ES, 11037/GR, 11037/BG, 11037/RO)<br>Klimakterie FSH-CHECK-1 (REF 11037BI, 11037/DK, 11037/DK1)<br>BARZA Test de menopauza (REF SC009)<br>FSH-CHECK-1 cassette (REF 11006C, 11076, 11076-4, 11076-MS-4, 11076/DE, 11076/ES, 11076/GR, 11076/BG, 11076/RO)<br>BARZA Test de infertilitate (REF SC010)<br>FSH-CHECK-1 Midstream, MENO-CHECK and its variants (REF 11066, 11066-11, 11066-12, 11084, 11066AO, 11084AV, 11066/IT, 11066/PT, 11066/HU, 11066/CZ, 11066/SK, 11066/HR, 11066/DE, 11066/ES, 11066/GR, 11066/BG, 11066/RO)<br>SloNO MENOPAUSA (REF 11066J)<br>FLOURISH MENOPAUSE TEST KIT (REF 11066BK)<br>Check4 Menopause (REF 11066AG)<br>Easy home Test Menopauze (REF IMP-10021)<br>SELFCheck menopause test (REF SCMEN2)<br>POLONORD ADESTE Test Menopauza (REF ADESTE-FSH1) | Self-testing<br>not Annex II |



  
Head of Certification Body

**Attachment of the certificate**

No. D1086900078

Date 2022-05-23

Page 6 of 12

| 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, 4084/PT, 4084/HU, 4084/CZ, 4084/SK, 4084/HR, 4084/DE, 4084/ES, 4084/GR, 4084/BG, 4084/RO)<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)<br>Patris Health - FIT Home Test (REF PATRIS-FIT-01)<br>POLONORD ADESTE Test sanguie occulto feci (REF ADESTE-FOB1)<br>Self Care Test rapid hemoragii oculte (FOB) (REF SC018)<br>POLY SelfTest (REF 4084AO2) | Self-testing 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, 70084/PT, 70084/HU, 70084/CZ, 70084/SK, 70084/HR, 70084/DK, 70084/DK1, 70084/DE, 70084/ES, 70084/GR, 70084/BG, 70084/RO)<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)<br>Patris Health - Lyme Disease Home Test (REF PATRIS-LYME-01)<br>POLONORD ADESTE Test Borreliosi (REF ADESTE-LYM1)<br>Self Care Test rapid boala Lyme (REF SC024)<br>TESTER Lyme-Tick Bite Test (REF 487525-EU-T)<br>LYME SelfTest (REF 70084AO2)   | Self-testing not Annex II |



  
 Head of Certification Body

**Attachment of the certificate**

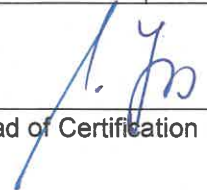
No. D1086900078

Date 2022-05-23

Page 7 of 12

| 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, 17084/PT, 17084/HU, 17084/CZ, 17084/SK, 17084/HR, 17084/DK, 17084/DK1, 17084/DE, 17084/ES, 17084/GR, 17084/BG, 17084/RO)<br>SLoNO 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)<br>Patris Health - Helicobacter pylori Home Test (REF PATRIS-HP-01)<br>POLONORD ADESTE Test Helicobacter pylori (REF ADESTE-HPY1)<br>Self Care Test rapid afectiuni ale stomacului (H. pylori) (REF SC020)<br>TESTER Helicobacter pylori Test (REF 487524-EU-T) | 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, 21084BA, 21084/IT1, 21084/PT, 21084/HU, 21084/CZ, 21084/SK, 21084/HR, 21084/DK, 21084/DK1, 21084/DE, 21084/ES, 21084/GR, 21084/BG, 21084/RO)<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)<br>Patris Health - Thyroid Function Home Test (REF PATRIS-TSH-01)<br>POLONORD ADESTE Test Tiroide (REF ADESTE-TSH1)<br>Self Care Test rapid afectiuni ale tiroidei (TSH) (REF SC023)<br>TESTER Thyro Test (REF 487523-EU-T)<br>THYRO SelfTest (REF 21084AO2)   | Self-testing not Annex II |



  
 \_\_\_\_\_  
 Head of Certification Body



**Attachment of the certificate**

No. D1086900078

Date 2022-05-23

Page 8 of 12

| Product category  | Product  | Class                     |
|---|--|---------------------------|
| Self-testing rapid test for the detection of gluten intolerance         | GLUTEN'ALARM and its variants (REF 150084, 150084AO, 150084AV, 150084BI, 150084/IT, 150084/IT1, 150084/PT, 150084/HU, 150084/CZ, 150084/SK, 150084/HR, 150084/DK, 150084/DK1, 150084/DE, 150084/ES, 150084/GR, 150084/BG, 150084/RO)<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)<br>Patris Health - Coeliac Disease Home Test (REF PATRIS-TTG-01)<br>POLONORD ADESTE Test Celiachia (REF ADESTE-GLU1)<br>Self Care Test rapid intoleranta la gluten (REF SC015) | 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, 25084BA, 25084/IT1, 25084/PT, 25084/HU, 25084/CZ, 25084/SK, 25084/HR, 25084/DK, 25084/DK1, 25084/DE, 25084/ES, 25084/GR, 25084/BG, 25084/RO)<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)<br>Patris Health - Anemia Home Test (REF PATRIS-ANEM-01)<br>POLONORD ADESTE Test Carezza Ferro (REF ADESTE-FER1)<br>Self Care Test rapid anemie (Fe) (REF SC014)  | Self-testing not Annex II |



  
 \_\_\_\_\_  
 Head of Certification Body

**Attachment of the certificate**

No. D1086900078

Date 2022-05-23

Page 9 of 12

| 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, 18084/IT, 18084/PT, 18084/HU, 18084/CZ, 18084/SK, 18084/HR, 18084/DE, 18084/ES, 18084/GR, 18084/BG, 18084/RO, 18084/IE)<br>Allergy test (REF MV88105-ALG)<br>SELFCheck ALLERGY TEST (REF SCIGE1)<br>ALLERGITEST ALLERGY-Check (REF 18084BI, 18084/DK, 18084/DK1)<br>Check4 Allergy (REF 18084AG)<br>Easy Home test Allergie (REF IMP-10006)<br>Patris Health - Allergy Home Test (REF PATRIS-ALRG-01)<br>POLONORD ADESTE Test Allergie (REF ADESTE-IGE1)<br>Self Care Test rapid alergii (REF SC011) | Self-testing not Annex II |
| Self-testing rapid test for the assessment of tetanus protection   | TETANOSTOP and its variants (REF 92084, 92084AO, 92084AV, 92084/IT, 92084/PT, 92084/DE, 92084/ES, 92084/GR, 92084/BG, 92084/RO, 92084/IE)<br>SELFCheck TETANUS TEST (REF SCTET1)<br>Check4 Tetanus Protection (REF 92084AG)<br>Easy Home Test Tetanus status (REF IMP-10032)<br>Patris Health - Tetanus Home Test (REF PATRIS-TET-01)<br>POLONORD ADESTE Test Tetano (REF ADESTE-TET1)  | Self-testing not Annex II |
| Self-testing rapid test for the detection of group A beta-hemolytic streptococcus bacteria in throat infection | STREPA'LERT and its variants (REF 6037, 6037BI, 6037AO, 6037AV, 6037/IT, 6037/PT, 6037/HU, 6037/CZ, 6037/SK, 6037/HR, 6037/DE, 6037/ES, 6037/GR, 6037/BG, 6037/RO, 6037/IE)<br>Check4 Strep Throat (REF 6037AG)<br>Easy home test Keelinfectie (REF IMP-10031)<br>Patris Health - Strep A Home Test (REF PATRIS-STRPA-01)<br>POLONORD ADESTE Test Streptococco A (REF ADESTE-STA1),<br>Self Care Test rapid Strep A (REF SC022)   | Self-testing not Annex II |



  
 Head of Certification Body

**Attachment of the certificate**

**No. D1086900078**

Date 2022-05-23

Page 10 of 12

| Product category  | Product   | Class                     |
|---|---|---------------------------|
| Self-testing rapid test for the detection of antibodies against Syphilis ( <i>Treponema pallidum</i> ) in whole blood | SYPH-CHECK-1 and its variants (REF 26084, 26184, 26084BI, 26084/PT, 26084/HU, 26084/CZ, 26084/SK, 26084/DE, 26084/ES, 26084/GR, 26084/BG, 26084/RO, 26084/IE)<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)<br>Patris Health - Syphilis Home Test (REF PATRIS-SYPH-01, PATRIS-SYPH-02)<br>POLONORD ADESTE Test Sifilide (REF ADESTE-SYP1)<br>TESTER Syphilis Test (REF 487526-EU-T)   | Self-testing not Annex II |
| Self-testing rapid test for the detection of C-reactive protein (CRP) in whole blood                                  | CRP-Screen and its variants (REF 34084, 34184, 34084AO, 34084BI, 34084/IT, 34084/PT, 34084/HU, 34084/CZ, 34084/SK, 34084/HR, 34084/DK, 34084/DK1, 34084/DE, 34084/ES, 34084/GR, 34084/BG, 34084/RO, 34084/IE)<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)<br>Patris Health - CRP Home Test (REF PATRIS-CRP-01)<br>POLONORD ADESTE Test Proteina C-reattiva (REF ADESTE-CRP1)<br>Self Care Test rapid proteina C reactiva (REF SC013) | Self-testing not Annex II |



  
 \_\_\_\_\_  
 Head of Certification Body

**Attachment of the certificate**

**No. D1086900078**

Date 2022-05-23

Page 11 of 12

| Product category  | Product   | Class                     |
|---|---|---------------------------|
| Strip immunochromatographic rapid test for self-testing of albumin in urine | M-ALBU-CHECK-1 Strip and its variants (REF 27037, 27037AO, 27037AV, 27037BE, 27037BI, 27037/IT, 27037/PT, 27037/HU, 27037/CZ, 27037/SK, 27037/HR, 27037/DK, 27037/DK1, 27037/DE, 27037/ES, 27037/GR, 27037/BG, 27037/RO),<br>SloNO ALBUMINA TEST (REF 27037J)<br>SELFCheck KIDNEY HEALTH TEST (REF SCALB1)<br>Check4 Kidney health (REF 27037AG)<br>Patris Health - Kidney Function Home Test (REF PATRIS-ALBU-01)<br>POLONORD ADESTE Test Insufficienza renale (REF ADESTE-MCA1)<br>Self Care Test rapid afectiuni ale rinichilor (REF SC017)  | Self-testing not Annex II |
| Self-testing assessment of liver physiological status in whole blood        | LIVER-SCREEN and its variants (REF 999984W-3L, 999984W-3L-AO, 999984W-3L/IT, 999984W-3L/PT, 999984W-3L/HU, 999984W-3L/CZ, 999984W-3L/SK, 999984W-3L/HR, 999984W-3L/DK, 999984W-3L/DK1, 999984W-3L/DE, 999984W-3L/ES, 999984W-3L/GR, 999984W-3L/BG, 999984W-3L/RO)<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)<br>Patris Health - Liver Function Home Test (REF PATRIS-LVR-01)<br>POLONORD ADESTE Test Fegato (REF ADESTE-LIV1)<br>Self Care Test rapid afectiuni ale ficatului (REF SC016)<br>Essentia Check (REF 220509E-13/CZ, 220509E-13/PL, 220509E-13/RO, 220509E-13/SK)<br>Esse Check (REF 220509E-09/CZ, 220509E-09/PL, 220509E-09/RO, 220509E-09/SK) | Self-testing not Annex II |



  
 \_\_\_\_\_  
 Head of Certification Body

**Attachment of the certificate**

**No. D1086900078**

Date 2022-05-23

Page 12 of 12

| Product category   | Product   | Class                     |
|--|---|---------------------------|
| Self-testing test for the detection of rotavirus and/or adenovirus in faeces                           | ROTADENO-Screen and its variants (REF 302984, 302984BI, 302984AO, 302984/PT, 302984/HU, 302984/CZ, 302984/SK, 302984/HR, 302984/DE, 302984/ES, 302984/GR, 302984/BG, 302984/RO)<br>Patris Health - Rotavirus-Adenovirus Home Test (REF PATRIS-RTAD-01)<br>POLONORD ADESTE Test Rotavirus Adenovirus (REF ADESTE-RTA1)<br>Self Care Test rapid rota-adenovirus (REF SC021)   | 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 and its variants (REF 200074-4/GB, 200074-4/FR, 200074-4/HU, 200074-4/CZ, 200074-4/SK, 200074-4/PL, 200074-4/LV, 200074-4/LT, 200074-4/EE, 200074-4/SW, 200074-4/PT, 200074-4/ES, 200074-4/IE, 200074-4/IT, 200074-4/DE, 200074-4/ES, 200074-4/GR, 200074-4/BG, 200074-4/RO, PATRIS-COVID19-AG)<br>SELFCheck COVID-19 Antigen Test (REF SCCOV2)<br>POLONORD ADESTE Test Covid Ag (REF ADESTE-COV1)<br>Self Care Test rapid antigen Covid-19 (REF SC012)                          | Self-testing not Annex II |
| Self-testing rapid test for the detection of faecal calprotectin associated to intestinal inflammation | CALPROTECTIN'ALERT and its variants (REF 63084/GB, 63084/FR, 63084/PL, 63084/HU, 63084/CZ, 63084/SK, 63084AO, 63084BI, 63084/IT, 63084/PT, 63084/HR, 63084/DE, 63084/ES, 63084/GR, 63084/BG, 63084/RO,63084/IE)<br>SELFCheck Inflammatory Bowel (REF SCIBD1)<br>PATRIS HEALTH - Calprotectin Home Test (REF PATRIS-CALPR-01)<br>MYBIO - Faecal Calprotectin Test (REF RTMYCP001)<br>POLONORD ADESTE Test Intestino irritabile (REF ADESTE-CAL1)<br>Self Care Test rapid afectiuni intestinale (REF SC025) | Self-testing not Annex II |



  
 \_\_\_\_\_  
 Head of Certification Body