

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


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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, 8084/IT, 8084/IT1, 8084/PT, 8084/HR, 8084/DE, 8084/ES, 8084/GR, 8084/BG, 8084/RO, 8084/IE) PSA-CHECK-1 HOMETEST (REF 8084AW, 8084AX, 8084AT, 8084/HU, 8084/CZ, 8084/SK) PROSTATA SCHNELLTEST (REF 8084T) PSA Test (REF 8084C) SloNO 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, 8084/DK, 8084/DK1) 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) POLONORD ADESTE Test Prostata (REF ADESTE-PSA1) Self Care Test rapid afectiuni ale prostatei (PSA) (REF SC019) PROSTA SelfTest (REF 8084AO2)	List B, Annex II




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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, 8091-S/HU, V040, V041, V045)	List B, Annex II
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
LH ovulation rapid test for self-testing	L-CHECK-1 STRIP (REF 5037, 5037/DE, 5037/ES, 5037/GR, 5037/BG, 5037/RO) Agglossning L-CHECK-1 (REF 5037BI) SloNO OVULAZIONE STRISCIA (REF 5037J) BARZA Test de ovulatie (REF SC008) 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) 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) SloNO OVULAZIONE STICK (REF 5066J) Check4 Ovulation (REF 5066AG) Easy Home test Ovulatie (REF IMP-10017) POLONORD ADESTE Test ovulazione (REF ADESTE-OVU1)	Self-testing not Annex II




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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) Check4 Pregnancy Whole blood test (REF 3184AG) SELFCheck Pregnancy Blood TEST (REF SCPBT1) PREGNASURE (REF VL3184BL) Patris Health - WB Pregnancy Home Test (REF PATRIS-HCGWB-01) POLONORD ADESTE Test Gravidanza su sangue (REF ADESTE-WBP1) BARZA Test de sarcina din sange (REF SC007)	Self-testing 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) MONO-TEST (REF 3003) BABYCHECK Plus (REF 3084) BABYCHECK Plus-10 (REF 3084-10) Check4 pregnancy Urine test+ (REF 3084AG) 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) 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) BABYCHECK Pregnancy Midstream Test (REF 3066/GR1, 3066-2T/GR1, 3066-10/GR1) dr. bosshammer-hCG (REF 3061-12-10B) JUMBO zwangerschapstest (REF 3061-11-10AY) leidapharm zwangerchapstest (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)	Self-testing not Annex II




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





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FSH menopause rapid test for self-testing	FSH-CHECK-1 Strip (REF 11037, 11036, 11037/DE, 11037/ES, 11037/GR, 11037/BG, 11037/RO) Klimakterie FSH-CHECK-1 (REF 11037BI, 11037/DK, 11037/DK1) BARZA Test de menopauza (REF SC009) FSH-CHECK-1 cassette (REF 11006C, 11076, 11076-4, 11076-MS-4, 11076/DE, 11076/ES, 11076/GR, 11076/BG, 11076/RO) BARZA Test de infertilitate (REF SC010) 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) 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) POLONORD ADESTE Test Menopauza (REF ADESTE-FSH1)	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, 4084/PT, 4084/HU, 4084/CZ, 4084/SK, 4084/HR, 4084/DE, 4084/ES, 4084/GR, 4084/BG, 4084/RO) FEC.O.TEST (REF 4084BC) SloNO 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) POLONORD ADESTE Test sangue occulto feci (REF ADESTE-FOB1) Self Care Test rapid hemoragii occulte (FOB) (REF SC018) 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) 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) POLONORD ADESTE Test Borreliosi (REF ADESTE-LYM1) Self Care Test rapid boala Lyme (REF SC024) TESTER Lyme-Tick Bite Test (REF 487525-EU-T) LYME SelfTest (REF 70084AO2)	Self-testing not Annex II





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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) SloNO 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) POLONORD ADESTE Test Helicobacter pylori (REF ADESTE-HPY1) Self Care Test rapid afectiuni ale stomacului (H. pylori) (REF SC020) 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) 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) POLONORD ADESTE Test Tiroide (REF ADESTE-TSH1) Self Care Test rapid afectiuni ale tiroidei (TSH) (REF SC023) TESTER Thyro Test (REF 487523-EU-T) THYRO SelfTest (REF 21084AO2)	Self-testing not Annex II




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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) 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) POLONORD ADESTE Test Celiachia (REF ADESTE-GLU1) 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) 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) POLONORD ADESTE Test Carenza Ferro (REF ADESTE-FER1) Self Care Test rapid anemie (Fe) (REF SC014)	Self-testing not Annex II




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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) Allergy test (REF MV88105-ALG) SELFCheck ALLERGY TEST (REF SCIGE1) ALLERGITEST ALLERGY-Check (REF 18084BI, 18084/DK, 18084/DK1) Check4 Allergy (REF 18084AG) Easy Home test Allergie (REF IMP-10006) Patris Health - Allergy Home Test (REF PATRIS-ALRG-01) POLONORD ADESTE Test Allergie (REF ADESTE-IGE1) Self Care Test rapid allergii (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) 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) 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) Check4 Strep Throat (REF 6037AG) Easy home test Keelinfectie (REF IMP-10031) Patris Health - Strep A Home Test (REF PATRIS-STRPA-01) POLONORD ADESTE Test Streptococco A (REF ADESTE-STA1), Self Care Test rapid Strep A (REF SC022)	Self-testing not Annex II




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Self-testing rapid test for the detection of antibodies against Syphilis (Treponema pallidum) 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) Syphilis Test (REF MV87979-SYP) VENERIS Test Rapid Sifilis (REF 26084BG) SELFCheck SYPHILIS TEST (REF SCSYP1) Check4 Syphilis (REF 26084AG) Easy Home test Syphilis (REF IMP-10020) Patris Health - Syphilis Home Test (REF PATRIS-SYPH-01, PATRIS-SYPH-02) POLONORD ADESTE Test Sifilide (REF ADESTE-SYP1) 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) 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) POLONORD ADESTE Test Proteina C-reattiva (REF ADESTE-CRP1) Self Care Test rapid proteina C reactiva (REF SC013)	Self-testing not Annex II




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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), 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) POLONORD ADESTE Test Insufficienza renale (REF ADESTE-MCA1) 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) 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) POLONORD ADESTE Test Fegato (REF ADESTE-LIV1) Self Care Test rapid afectiuni ale ficatului (REF SC016) Essentia Check (REF 220509E-13/CZ, 220509E-13/PL, 220509E-13/RO, 220509E-13/SK) Esse Check (REF 220509E-09/CZ, 220509E-09/PL, 220509E-09/RO, 220509E-09/SK)	Self-testing not Annex II




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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) Patris Health - Rotavirus-Adenovirus Home Test (REF PATRIS-RTAD-01) POLONORD ADESTE Test Rotavirus Adenovirus (REF ADESTE-RTA1) 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) SELFCheck COVID-19 Antigen Test (REF SCCOV2) POLONORD ADESTE Test Covid Ag (REF ADESTE-COV1) 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) SELFCheck Inflammatory Bowel (REF SCIBD1) PATRIS HEALTH - Calprotectin Home Test (REF PATRIS-CALPR-01) MYBIO - Faecal Calprotectin Test (REF RTMYCP001) POLONORD ADESTE Test Intestino irritabile (REF ADESTE-CAL1) Self Care Test rapid afectiuni intestinale (REF SC025)	Self-testing not Annex II





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