

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**PRIMA Lab SA
Via Antonio Monti 7
6828 Balerna
Switzerland**

for the scope

**Testing devices for the detection of
anti-HIV 1 and 2 antibodies, prostate specific antigen PSA,
blood glucose and rapid self-testing devices
(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	2022-05-18
Valid until	2025-05-26
Registration no.	D1408400052
Report no.	P22-00865-237932
Stuttgart	2022-05-18


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. D1408400052

Date 2022-05-18

Page 1 of 8

Product category	Product	Class
Immuno-chromatographic rapid self-testing devices for the detection of anti-HIV 1 and 2 antibodies	HIV 1/2 Self-Test (REF 800062-1, 800062-1ES, 800062-1H, 800062-1PB) EASY CARD® HIV SELF TEST (REF 870062-1) berkeleyhealth HIV (REF 890062-1)	List A, Annex II
Immuno-chromatographic rapid self-testing devices for the detection of prostate specific antigen PSA	Prostate PSA Test (REF 800080-x) MyTest Prostate, MyTest Prostaat (REF 380080) Profar Test PSA (REF 801080) EASY CARD® PSA SELF TEST (REF 870080-x) berkeleyhealth Prostate PSA (REF 890080-x)	List B, Annex II
Self-testing system device for the detection of blood glucose	Avanti Blood Glucose Meter / Medidor de Glucosa en Sangre (REF PL700) Avanti Blood Glucose Test Strips / Tiras de Prueba de Glucosa en Sangre (REF PL701) Avanti Blood Glucose Control Solution / Solución de control de Glucose (REF PL705)	List B, Annex II
Immuno-chromatographic rapid self-testing devices for the assessment of tetanus protection	Tetanus Test (REF 800092-x) MyTest Tétanos (REF 380092) EASY CARD® TETANUS SELF TEST (REF 870092-x) berkeleyhealth Tetanus (REF 890092-x)	Self-testing not Annex II
Immuno-chromatographic rapid self-testing devices for the detection of antibodies against Helicobacter pylori	Helicobacter pylori Test (REF 800017-x) MyTest H.pylori-Estomac, MyTest Magen-Vorsorge (H.pylori) (REF 380017) berkeleyhealth Helicobacter pylori (REF 890017-x)	Self-testing not Annex II
Immuno-chromatographic rapid self-testing devices for H. pylori detection in stools	Helicobacter pylori Antigen Test (REF 800016-x) TEST AUTODIAGNOSTICO HELICOBACTER PYLORI (REF 801016) EASY CARD® HELICOBACTER SELF TEST (REF 870016-x) berkeleyhealth Helicobacter pylori antigen (REF 890016-x)	Self-testing not Annex II
Immuno-chromatographic self-testing devices for detection of Group A beta-hemolytic streptococcus bacteria in throat infection	STREP A TEST (REF 800060-x) PROFAR STREP A TEST (REF 801060-x) EASY CARD® STREP A SELF TEST (REF 870060-x) berkeleyhealth Strep A (REF 890060-x)	Self-testing not Annex II





 Head of Certification Body

Attachment of the certificate

No. D1408400052

Date 2022-05-18

Page 2 of 8

Product category	Product	Class
Immunochematographic rapid self-testing devices for the detection of SARS-CoV-2 antigens in nasal swab samples or oral fluid specimens	COVID-19 Oral Fluid Self-Test (REF 100071-x) COVID-19 Antigen Self-Test (Oral Fluid) (REF 100171-x) COVID-19 Oral Fluid Antigen Test (REF 100271-x) COVID-19 Saliva Self-Test (REF 100371-x) COVID-19 Antigen Self-Test (REF 200063-x) COVID-19 Self-Test (REF 210063-x) SARS-CoV-2 Antigen Self-Test (REF 220063-x) COVID-19 Nasal Self-Test (REF 230063-x) PRIMACOVID COVID-19 Nasal Self-Test (REF 900063-x) PRIMACOVID COVID-19 Self-Test (REF 900163-x) EASY CARD® COVID-19 SALIVA SELF TEST (REF 170371-x) EASY CARD® COVID-19 ANTIGEN SELF TEST (REF 970063-x)	Self-testing not Annex II
Immunochematographic rapid self-testing devices for the detection of SARS-CoV-2 specific antibodies in human capillary blood	COVID-19 Serological Test (REF 800061-x) Serological Self Test COVID (REF 800161-x) COVID-19 Antibody Self Test (REF 800261-x) COVID-19 IgG Self-Test (REF 800069-x) PRIMACOVID IgG Serological Test (REF 800169-x) COVID-19 IgG Spike Self-Test (REF 800065-x) COVID-19 Neutralizing IgG Serological Test (REF 800165-x) Post Vaccine Test (REF 800265-x) EASY CARD® COVID-19 S-1 SEROLOGICAL SELF TEST (REF 870165-x) EASY CARD® COVID-19 NC SEROLOGICAL SELF TEST (REF 870061-x)	Self-testing not Annex II
Colorimetric rapid self-testing devices for the semi-quantitative determination of pH in female vaginal swab specimens	Vaginal pH Test (REF 100013-x) DeoDoc Vaginal pH test (REF 910013-x) EASY CARD® VAGINAL pH SELF TEST (REF 170013-x) berkeleyhealth Vaginal pH (REF 190013-x)	Self-testing not Annex II





 Head of Certification Body

Attachment of the certificate

No. D1408400052

Date 2022-05-18

Page 3 of 8

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Colorimetric rapid self-testing device for in vitro qualitative estimation of sperm concentration in human semen	Sperm Test (REF 100082-x) DeoDoc Sperm test (REF 910082-x) EASY CARD® SPERM SELF TEST (REF 170082-x) berkeleyhealth Sperm count (REF 190082-x)	Self-testing not Annex II
Colorimetric rapid self-testing device for the semi-quantitative detection of Vitamin D in human whole blood	Vitamin D Test (REF 100066-x) Test Autodiagnostico Vitamina D (REF 101166-x) CASC VITAMIN D TEST (REF 105066-x) EASY CARD® VITAMIN D SELF TEST (REF 170066-x) berkeleyhealth Vitamin D (REF 190066-x)	Self-testing not Annex II
Immunochromatographic rapid self-testing devices for the detection of luteinizing hormone LH	Ovulation LH Test (REF 800050-x) Test di ovulazione Securtest® (REF 801050, 821050) Safe&Easy Ovulationstest (REF 803150-x, 823150-x) Ovulation LH Test (REF 820050-x) DeoDoc Ovulation test (REF 910050-x) EASY CARD® OVULATION SELF TEST (REF 870050-x) berkeleyhealth Ovulation LH (REF 890050-x)	Self-testing not Annex II
Immunochromatographic rapid self-testing devices for the detection of human chorionic gonadotropin hCG	Pregnancy hCG Test (REF 800030-x) HIGHMED Technology - Pregnancy Test (REF 805030) Pharmadoc - Pregnancy Test (REF 815030) DoctPharma Pregnancy Test (REF 835030-x) Setablu Pregnancy Test (REF 845030-x) Pregnancy hCG Test (REF 820030-x) GSV Pregnancy Test (REF 855030-x) SUNLUX® Diagnostic – TEST DI GRAVIDANZA (REF 865030-x)	Self-testing not Annex II





 Head of Certification Body

Attachment of the certificate

No. D1408400052

Date 2022-05-18

Page 4 of 8

Product category	Product	Class
Immunochemical rapid self-testing devices for the early detection of hCG in urine	Early Pregnancy Test (REF 800010-x) Early Pregnancy Test (REF 820010-x) Early Pregnancy Test (REF 825010-x) LA NUOVA PHARMACIA Early Pregnancy Test (REF 855010-x) MD MEDICAL Early Pregnancy Test (REF 815110-x) MEGAPLAST Early Pregnancy Test (REF 815210-x) PRONTOMED Early Pregnancy Test (REF 815310-x) MEDIPRO DESPAR Early Pregnancy Test (REF 815410-x) PAMPHARMA Early Pregnancy Test (REF 815510-x) PRIMIA Early Pregnancy Test (REF 815610-x) FORSE SI-FORSE NO Early Pregnancy Test (REF 815710-x) PiúME MEDICAL Early Pregnancy Test (REF 845010-x) DERMOPLAST Early Pregnancy Test (REF 815810-x) CONFIDERM Early Pregnancy Test (REF 815910-x) ESSERE BENESSERE Early Pregnancy Test (REF 825110-x) IPER LA GRANDE I Early Pregnancy Test (REF 825210-x) SELEX Early Pregnancy Test (REF 825310-x) DIAGNOSTIC TEST Early Pregnancy Test (REF 825410-x) SICURA Early Pregnancy Test (REF 825510-x) PARAFARMACIA CONAD Early Pregnancy Test (REF 825610-x)	Self-testing not Annex II



 Head of Certification Body



Attachment of the certificate

No. D1408400052

Date 2022-05-18

Page 5 of 8

Product category	Product	Class
Immunochromatographic rapid self-testing devices for the early detection of hCG in urine	COOP Early Pregnancy Test (REF 825710-x) U CONFORTA & RISPARMIA Early Pregnancy Test (REF 825810-x) CONSILIA SAPER SCEGLIERE Early Pregnancy Test (REF 825910-x) CARREFOUR Early Pregnancy Test (REF 835110-x) FARMA Early Pregnancy Test (REF 835210-x) BENNET Early Pregnancy Test (REF 835310-x) I MEDICALI Early Pregnancy Test (REF 835410-x) PHARMA Early Pregnancy Test (REF 835510-x) LLOYDSPHARMACY Early Pregnancy Test (REF 835610-x) Sanavita Test di Gravidanza (REF 823010-x) FirstPraedict® CARE FOR YOU® (REF 826010-x) DeoDoc Early Pregnancy test (REF 910010-x) EASY CARD® PREGNANCY SELF TEST (REF 870010-x) berkeleyhealth Early Pregnancy (REF 890010-x)	Self-testing not Annex II
Immunochromatographic rapid self-testing devices for the detection of follicle stimulating hormone FSH	Menopause FSH Test (REF 800011-x) MyTest Ménopause, MyTest Menopause, Estromineral MyTest - Menopausa (REF 380011, 382011) Menopause FSH Test (REF 820011-x) DeoDoc Menopause test (REF 910011-x) EASY CARD® MENOPAUSE SELF TEST (REF 870011-x) berkeleyhealth Menopause FSH (REF 890011-x)	Self-testing not Annex II
Immunochromatographic rapid self-testing device for C-reactive protein levels in blood	C-Reactive Protein Test (REF 800034-x) CRP Test (REF 880034-x) EASY CARD® CRP SELF TEST (REF 870034-x) berkeleyhealth C-Reactive Protein (REF 890034-x)	Self-testing not Annex II



 Head of Certification Body



Attachment of the certificate

No. D1408400052

Date 2022-05-18

Page 6 of 8

Product category	Product	Class
Immuno-chromatographic rapid self-testing devices for the detection of TSH level in blood	Thyroid TSH Test (REF 800021-x) MyTest Thyroide (REF 380021) TEST AUTODIAGNOSTICO TSH (REF 801021) EASY CARD® TSH SELF TEST (REF 870021-x) berkeleyhealth Thyroid TSH (REF 890021-x)	Self-testing not Annex II
Immuno-chromatographic rapid self-testing devices for urinary albumin	Kidneys Albumin Test (REF 800027-x, 820027-x) MyTest Albumine (REF 380027, 382027) EASY CARD® ALBUMIN SELF TEST (REF 870027-x) berkeleyhealth Kidney Albumin (REF 890027-x)	Self-testing not Annex II
Urine dipstick devices for self-testing for urinary tract infections	Urinary Tract Infections Test (REF 100058-x) MyTest Infection Urinaire, MyTest Harnwegsinfekt, MyTest Urineweg-infectie (REF 300058) Vidi Pharma Selvtest Urinveisinfeksjon (REF 102058-x) DeoDoc Urinary tract infection test (REF 910058-x) EASY CARD® URINARY TRACT INFECTIONS SELF TEST (REF 170058-x) berkeleyhealth Urinary Tract Infection (REF 190058-x)	Self-testing not Annex II
Immuno-chromatographic rapid self-testing devices for the detection of Ferritin level in blood	Iron Fer Test (REF 800025-x) MyTest Jern, MyTest - Ferro, MyTest Eisenmangel, MyTest Fer (REF 380025) FerriCheck (REF 802025) Test Autodiagnostico Ferro (REF 801025-x) CASC Eisen Schnelltest (REF 805025-x) EASY CARD® FERRITIN SELF TEST (REF 870025-x) berkeleyhealth Iron FER (REF 890025-x)	Self-testing not Annex II
Immuno-chromatographic rapid self-testing devices for the detection of blood in faeces	Bowel FOB Test (REF 800040-x) MyTest Intestinal (REF 380040) Profar Test Colon Retto (REF 801040) EASY CARD® FOB SELF TEST (REF 870040-x) berkeleyhealth Bowel FOB (REF 890040-x)	Self-testing not Annex II




 Head of Certification Body

Attachment of the certificate

No. D1408400052

Date 2022-05-18

Page 7 of 8

Product category	Product	Class
Dry-chemistry rapid self-testing devices for total cholesterol level detection	Cholesterol Test (REF 100049-x) MyTest Cholestérol, MyTest Cholesterol, Armolipid MyTest - Colesterolo, MyTest Cholesterin (REF 300049) COLLIPID (REF 400049)	Self-testing not Annex II
Self-testing device system for the detection of cholesterol in whole blood	Avanti Lipid Panel Meter / Medidor de Perfil de Lípidos (REF PL600) Avanti Cholesterol Test Devices 3-in-1 Lipid Panel / Dispositivos de Prueba Panel de Lípidos 3 en 1 (REF PL601) Avanti Cholesterol Test Devices CHOL Total Cholesterol / Dispositivos de Prueba CHOL Colesterol Total (REF PL 602) Cholesterol Test Devices TRIG Triglycerides / Dispositivos de Prueba TRIG Trigliceridos (REF PL603) Cholesterol Control devices / Dispositivos de Control de Colesterol Total (REF PL604) Cholesterol Control Solution / Solución de Control de Colesterol (REF PL605) Capillary Transfer Tubes (10µL) / Tubos de Transferencia Capilar (REF PL606) Capillary Transfer Tubes (35µL) / Tubos de Transferencia Capilar (REF PL607) Avanti Ultra Cholesterol Monitoring System / Sistema de Monitoreo de Colesterol (REF PL800) Avanti Ultra Total Cholesterol Test strips / Tiras de prueba de Colesterol Total (REF PL801) Cholesterol Control Solution / Solución de Control de Colesterol (REF PL805)	Self-testing not Annex II





 Head of Certification Body

Attachment of the certificate

No. D1408400052

Date 2022-05-18

Page 8 of 8

Product category	Product	Class
Immunochematographic rapid self-testing devices for the detection of possibly leakage of amniotic fluid	AMNIOCHECK (REF 100088-5, 100088-x) AMNIOSENSE (REF 100088-10) SAUGELLA AmnioCheck (REF 300088) AMNIOS (REF 600088) AMNIODETECT (REF 700088) AL-SENSE (REF 900088-2, 900088-50) Barza Amniotest (REF 710088) berkeleyhealth Amniotic Fluid (REF 190088-x)	Self-testing not Annex II
Immunochematographic rapid self-testing devices for celiac disease screening	Celiac Test (REF 100077-x) MyTest Maladie coeliaque, MyTest Glutenintoleranz, MyTest - Celiachia (REF 300077) Test Autodiagnostico Celiachia (REF 101177-x) EASY CARD® CELIAC SELF TEST (REF 170077-x) berkeleyhealth Celiac (REF 190077-x)	Self-testing not Annex II
Immunochematographic rapid self-testing devices for the detection of total IgE	Allergy IgE Test (REF 800018-x) MyTest Allergie, MyTest Allergi, MyTest Allergia (REF 380018) EASY CARD® ALLERGY SELF TEST (REF 870018-x) berkeleyhealth Allergy IgE (REF 890018-x)	Self-testing not Annex II
Immunochematographic rapid self-testing devices for the detection of specific IgE anti House Dust Mite	ExAller® Dust Mite Allergy Self-Test (REF 800015) House Dust Mite Allergy Self-Test (REF 880015-x) EASY CARD® DUST MITE ALLERGY SELF TEST (REF 870015-x)	Self-testing not Annex II





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