

# 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  
prostate specific antigen PSA 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	2020-10-28
Valid until	2021-01-18
Registration no.	D1408400027
Report no.	P20-01122-180568
Stuttgart	2020-10-28



Head of Certification Body



**Attachment of the certificate**

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Product category	Product	Class
Immunochromatographic 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)	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
Immunochromatographic rapid self-testing devices for the assessment of tetanus protection	Tetanus Test (REF 800092-x) MyTest Tétanos (REF 380092)	Self testing not Annex II
Immunochromatographic 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)	Self testing not Annex II
Immunochromatographic rapid self-testing devices for H. pylori detection in stools	Helicobacter pylori Antigen Test (REF 800016-x) TEST AUTODIAGNOSTICO HELICOBACTER PYLORI (REF 801016)	Self testing not Annex II
Immunochromatographic 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)	Self testing not Annex II
Immunochromatographic rapid self-testing devices for the detection of SARS-CoV-2 specific antibodies in human capillary blood	COVID-19 Serological Test (REF 800061-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)	Self testing not Annex II



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Product category	Product	Class
Colorimetric rapid self-testing device for in vitro qualitative estimation of sperm concentration in human semen	Sperm Test (REF 100082-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)	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)	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) Pharmadoct - Pregnancy Test (REF 815030) DoctPharma Pregnancy Test (REF 835030-x)	Self testing not Annex II
Immunochromatographic rapid self-testing devices for the early detection of hCG in urine	Early Pregnancy Test (REF 800010-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)	Self testing not Annex II



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Immunochromatographic rapid self-testing devices for the early detection of hCG in urine	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) 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)	Self testing not Annex II



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Product category	Product	Class
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)	Self testing not Annex II
Immunochromatographic rapid self-testing device for C-reactive protein levels in blood	C-Reactive Protein Test (REF 800034-x)	Self testing not Annex II
Immunochromatographic rapid self-testing devices for the detection of TSH level in blood	Thyroid TSH Test (REF 800021-x) MyTest Thyroïde (REF 380021) TEST AUTODIAGNOSTICO TSH (REF 801021)	Self testing not Annex II
Immunochromatographic rapid self-testing devices for urinary albumin	Kidneys Albumin Test (REF 800027-x) MyTest Albumine (REF 380027)	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)	Self testing not Annex II
Immunochromatographic 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)	Self testing not Annex II
Immunochromatographic 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)	Self testing not Annex II
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



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Product category	Product	Class
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
Immunochromatographic 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)	Self testing not Annex II



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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)	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)	Self testing not Annex II
Immunochematographic rapid self-testing devices for the detection of specific IgE anti House Dust Mite	ExAller <sup>®</sup> Dust Mite Allergy Self-Test (REF 800015)	Self testing not Annex II



A handwritten signature in blue ink, consisting of a series of loops and a long horizontal stroke.

Head of Certification Body